



# Toward National Uniformity for FDA-Regulated Products

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# ***TOWARD NATIONAL UNIFORMITY FOR FDA-REGULATED PRODUCTS***

By Amy Elizabeth Semet

## **I. Introduction**

Since 1906, the Food and Drug Administration (“FDA”) has been the primary guardian of the safety of the nation’s food and drug supply. Every year, FDA’s 2,100 scientists and 7,000 other employees monitor about \$1 trillion worth of products, inspect 15,000 facilities, and examine 80,000 product samples.<sup>1</sup> Despite the comprehensiveness of FDA regulation, states have assumed the role of “mini-FDAs,”<sup>2</sup> in supervising the regulation of drugs, medical devices, cosmetics, and food. States have allowed their legislatures and their courts to supersede FDA determinations of safety and efficacy. Manufacturers of FDA-regulated products, faced with forced compliance with different domestic and international regulatory regimes, and in defending products liability suits, must often meet standards of care that exceed what the FDA requires.

To combat this trend, in 1997, Congress passed the Food and Drug Administration Modernization Act (“FDAMA”)<sup>3</sup> in order to mandate “national uniformity” for the regulation of over-the-counter (“OTC”) drugs and cosmetics.<sup>4</sup> Under FDAMA, states may not pass “any requirement” that differs from federal standards for OTC drugs.<sup>5</sup> In contrast, state labeling on cosmetics is preempted, but states remain free to

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<sup>1</sup>143 CONG. REC. S9842 (Sept. 24, 1997) (statement of Sen. Feinstein).

<sup>2</sup>*Hearing on the FDA Approval Process Before the Subcommittee on Health and Environment of the Committee on Commerce*, 103<sup>rd</sup> Cong., (May 2, 1996) (statement of James D. Cope, President of the Nonprescription Drug Manufacturers Association).

<sup>3</sup>Pub. L. No. 105-115, 111 Stat. 2296 (1997).

<sup>4</sup>21 U.S.C. § 379r; FDAMA § 412; FDCA § 751(a); 21 U.S.C. § 379s; FDAMA § 412(d); FDCA § 752(a).

<sup>5</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(a). “In general, [e]xcept as provided in subsection (b) (c)(1), (d), (e) or

pass cosmetic safety standards as long as the federal government has not acted.<sup>6</sup> Why is there a difference in the preemption standards for OTC drugs and cosmetics? As Senator Jeffords noted during the FDAMA debates, OTCs are not “any different” from cosmetics for “all intents and purposes,” yet preemption of OTCs was not nearly as objectionable as preemption of cosmetics.<sup>7</sup> Further, the enactment of the national uniformity provisions of FDAMA was not the first time that Congress mandated divergent preemption standards for different FDA-regulated products. The 1990 Nutrition Labeling and Education Act (“NLEA”)<sup>8</sup> preempted state labeling requirements for food, but allowed states to regulate safety standards exceeding those of the FDA.<sup>9</sup> Legislation has recently been introduced to expand the spirit of the NLEA to preclude state requirements relating to food safety.<sup>10</sup> Medical devices are another case in point. Nearly 25 years ago – long before FDAMA mandated national uniformity for OTC drugs and cosmetics – Congress enacted the 1976 Medical Device Amendments (“MDA”)<sup>11</sup> to preempt state requirements dealing with medical devices.<sup>12</sup>

Even where the FDA has mandated national uniformity in product labels or safety standards, states retain the power to enforce higher standards through state product liability suits. Significantly, lawsuits alleging failure-to-warn are not generally preempted by compliance with uniform, FDA-mandated national standards.<sup>13</sup>

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(f), no State or political subdivision of a State may establish or continue in effect any requirement –

1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and  
 2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Packaging Act of 1970 [15 U.S.C. § 1471 et seq.], or the Fair Packaging and Labeling Act [15 U.S.C. § 1451 et seq.]”

<sup>6</sup>21 U.S.C. § 379(s); FDAMA § 412(d); FDCA § 752(a). “In general, [e]xcept as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 [15 U.S.C. § 1471 et seq.], or the Fair Packaging and Labeling Act [15 U.S.C. § 1451 et seq.]”

<sup>7</sup>143 CONG. REC. S8894 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>8</sup>Pub. L. No. 101-535, 104 Stat. 2353 (1990); 21 U.S.C. § 343-1.

<sup>9</sup>*See infra* pp. 67-68.

<sup>10</sup>*See infra* pp. 71-72

<sup>11</sup>Pub. L. No. 94-295, 90 Stat. 540 (1976).

<sup>12</sup>21 U.S.C. § 360k. Section 360(k) states: “Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement — 1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and 2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the Act;” *see infra* 10-12.

<sup>13</sup>*See J. Warren Rissier, The FDA’s Proposed Labeling Rules for Over-the-Counter Drugs and Preemption of State Tort Law,*

FDAMA explicitly states that state product liability suits dealing with OTC drugs or cosmetics are not preempted by the national uniformity provisions.<sup>14</sup> The preemption analysis is different for medical devices. Courts have construed the preemption provisions of the MDA to preclude state tort liability for medical devices; to date, neither the FDA nor Congress has explicitly set the record straight on whether state court juries should override FDA determinations of safety for medical devices.<sup>15</sup> In fact, the FDA recently withdrew a proposed rule which would have clarified that state product liability rules are not preempted by the MDA.<sup>16</sup> Similar to the issue of national uniformity, the question remains as to whether it makes sense to allow for federal preemption of state tort liability of some FDA-regulated products but not others. As one U.S. Supreme Court justice asked during the oral argument of Medtronic Inc., v. Lohr,<sup>17</sup> “Isn’t it odd... that with an agency that is charged with regulating food, drugs, medical devices, that Congress would create a regime that ousts State tort remedies for medical devices but not for drugs, not for food, not for cosmetics? Why would Congress do that?”<sup>18</sup>

In this paper, I will argue that national uniformity should be granted to all FDA-regulated products and should include preemption of both state labeling and safety standards as well as state product liability laws. Cosmetics and food should be treated the same as FDAMA treats OTC drugs. Although the FDA has developed different regulatory regimes for each product, the FDA has established the optimal standards for all of its products, and states should not interfere to preclude harmonization. Congress should also prevent

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71 SO. CAL. L. REV. 1387, 1389 (1998).

<sup>14</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(e). For OTC drugs, § 751(e) reads, “No Effect on Product Liability Law – Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State;” *see also* 21 C.F.R. § 379s; FDAMA § 412(a); FDCA § 752 (d). For cosmetics, § 752(d) reads, “No Effect on Product Liability Law – Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”

<sup>15</sup>*See infra* pp. 9-12, 38-41.

<sup>16</sup>Withdrawal of Proposed Rule, 63 Fed. Reg. 39789 (July 24, 1998).

<sup>17</sup>Medtronic, Inc., v. Lohr, 116 S.Ct. 2240 (1996).

<sup>18</sup>Transcript of Oral Arg., Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996) (Nos. 95-754 and 95-886), available in 1996 WL 207143, at \*26. Professor Arthur Miller of Harvard Law School argued on behalf of Medtronic, Inc. before the United States Supreme Court. *See id.* at \*1.

state courts and lay juries from interfering with the goals of the FDA to both ensure the safety of products, while at the same time, encourage innovation. The Supreme Court has said, “state regulations can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”<sup>19</sup> Congress needs to recognize that state tort claims impose requirements for safety and effectiveness that can be just as detrimental to the goals of national uniformity as state labeling and safety standards.<sup>20</sup> The benefits of national uniformity for FDA-regulated products can never be fully realized if state tort suits interfere as an additional regulatory tool to monitor safety. FDAMA itself is inherently contradictory, because the explicit allowance of state tort suits conflicts with the Act’s goal of national uniformity.<sup>21</sup> Manufacturers are caught in a “physical impossibility,”<sup>22</sup> because even if manufacturers comply with nationally uniform FDA standards, the threat of tort liability results in an incentive to overwarn and to include information that departs from a uniform FDA standard.<sup>23</sup>

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<sup>19</sup>*Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2620 (1992), citing *San Diego Bldg. Trades Council v. Garman*, 359 U.S. 236, 247 (1959).

<sup>20</sup>*See King v. Collagen*, 983 F.2d 1130, 1135 (1<sup>st</sup> Cir. 1993) (“Appellant’s claim would force us to determine that [the product] is unsafe and dangerous, in opposition to the contrary determination made by the FDA.”)

<sup>21</sup>*See Rissier*, *supra* note 13, at 1393-1394.

<sup>22</sup>*See id.* “Perhaps the reason why the FDA failed to preempt state tort law is that it failed to recognize the extent to which compliance with both FDA standards and state tort law is a physical impossibility, and the degree to which state law stands as an obstacle to the accomplishment of effective labeling of OTC drugs and providing for affordable healthcare.” *Id.* (citing 62 Fed. Reg. 9024, 9041 (1997)).

<sup>23</sup>*See id.*

## II. The Doctrine of Federal Preemption and the Statutory Compliance Defense

The Constitution's Supremacy Clause necessitates that federal law take precedence over state or local law.<sup>24</sup>

One commentator defined preemption as “the authority granted to the Congress by the U.S. Constitution to assume partial or total responsibility for a governmental function, thereby delimiting the roles of the states and their political subdivisions.”<sup>25</sup> Since the ratification of the Constitution in 1789, Congress has passed over 350 statutes preempting state laws.<sup>26</sup> Indeed, the increase in the number of fields preempted by the federal government is staggering. Of the 350 preempted laws, all but 14 had been enacted in the past 100 years, and more than half in the past 30 years.<sup>27</sup> The New Deal, the civil rights movement, and consumer protection have been favored areas of federal preemption.<sup>28</sup>

Courts have recognized two kinds of preemption: express and implied.<sup>29</sup> Express preemption occurs when Congress clearly indicates that federal law should preempt state regulations.<sup>30</sup> Federal agencies can also establish regulations which preempt state law. For example, in 1986, the FDA expressly preempted state-imposed requirements on aspirin if the state labeling conflicted with the FDA requirements.<sup>31</sup> In the absence of express statutory language, courts may also imply preemption. In implying preemption, courts look to 1)

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<sup>24</sup>See U.S. Const., art. VI., cl.2. The Supremacy Clause provides: “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in each State shall be bound thereby, any Thing in the Constitution or Law of any State to the Contrary notwithstanding.” *Id.*

<sup>25</sup>Joseph F. Zimmerman, *FEDERAL PREEMPTION: THE SILENT REVOLUTION* 3 (1991).

<sup>26</sup>See W. John Moore, *Stopping the Stones*, *THE NATIONAL J.* (July 21, 1990), at 1758.

<sup>27</sup>See *id.*

<sup>28</sup>See *id.* For instance, age discrimination acts, and fair housing and voting rights statutes all contained preemption language. See *id.* In the consumer protection arena, the federal government has passed statutes establishing federal preemption for air and water quality, asbestos removal, drug abuse control, hazardous substances, mine safety, nuclear emergency planning, and cigarette smoking, among others. See *id.*

<sup>29</sup>For a detailed discussion of federal preemption, see Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 *FOOD & DRUG L. J.* 510-524 (1996).

<sup>30</sup>See, e.g., *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (local regulations preempted by Federal Meat Inspection Act).

<sup>31</sup>See *Labeling of Oral and Rectal Over-the-Counter Aspirin and Aspirin Containing Products*, Final Rule, 55 *Fed. Reg.* 27,776 (1990); see also Marilyn P. Westerfield, *Federal Preemption and the FDA: What Does Congress Want*, 58 *U. CIN. L. REV.* 263, 265 (1989).

the comprehensiveness of federal regulations; 2) the dominant federal interest in the subject matter regulated; and 3) whether there exists a direct conflict between federal and state requirements.<sup>32</sup> Courts, however, have been reluctant to imply preemption, especially for FDA-regulated products.<sup>33</sup>

Where preemption cannot be raised as a defense, defendants in product liability suits may assert a “statutory compliance defense.” There is a “fine line” between the preemption doctrine and the statutory compliance defense.<sup>34</sup> Manufacturers can assert a preemption defense when a federal agency’s regulations supersede all other laws.<sup>35</sup> Manufacturers complying with all federal regulations in a preempted industry are immune from tort liability.<sup>36</sup> In contrast, manufacturers complying with federal regulations in industries where the preemption defense does not apply will not necessarily be immune from tort liability.<sup>37</sup> They will only be immune if a jury finds them nonnegligent because of their compliance with federal safety standards.<sup>38</sup> Courts have been reluctant to allow manufacturers to escape liability under a statutory compliance defense. In most cases, courts generally view compliance as “evidence of, or at the most a rebuttable presumption of, nonnegligence regarding the manufacturing or design defects of a product.”<sup>39</sup> Some states, however, have

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<sup>32</sup>See *e.g.*, *Hillsborough County, Fla. v. Automated Med. Lab.*, 471 U.S. 707, 713 (1985) (refused to imply preemption where introduce no evidence that county blood centers interfered with federal goals); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (discussing the factors that give rise to implied congressional occupation of a particular area); *see also* *Westerfield*, *supra* note 31, at 266-270.

<sup>33</sup>See, *e.g.*, *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4<sup>th</sup> Cir. 1988) ( “preemption [did] not follow immediately from the comprehensive federal regulation of prescription biological products.”); *see also* David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 407-421 (1996). Courts, however, have implied preemption in other fields. For instance, in *Campbell v. Hussey*, 368 U.S. 297 (1961), the Supreme Court said that the Tobacco Inspection Act preempted state classifications for tobacco because the federal statute specifically dealt with the subject matter. *See id.* at 302.

<sup>34</sup>See Ashley W. Warren, *Compliance With Governmental Regulatory Standards: Is It Enough to Immunize a Defendant from Tort Liability?*, 49 BAYLOR L. REV. 763, 771 (1997).

<sup>35</sup>See *id.* at 772; *see also* *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 369 (1986).

<sup>36</sup>See Warren, *supra* note 34, at 772.

<sup>37</sup>See *id.*

<sup>38</sup>See *id.*

<sup>39</sup>See *id.* Courts first addressed the statutory compliance defense in cases dealing with public safety concerns about governmental regulation of the railroads. *See id.* at 773. For instance, in *Grand Truck Railroad Co., v. Ives*, 144 U.S. 408 (1892), the Supreme Court held that railroads could be liable for negligence even if they had complied with federal safety regulations prescribing the nature and placing of crossing signals, and other precautionary measures, designed to ensure the public safety. *See id.* at 420-421. Manufacturers, however, would have a defense against tort liability if there existed no extraordinary hazards. *See id.* at 421. The Second Restatement of Torts embraced the holding of *Ives*. *See* Warren, *supra* note 34, at 777. The Restatement states that “[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.” Restatement (Second) of Torts, §288 (C) (1965).

modified the common law by enacting statutes that create a presumption that regulatory compliance suffices to establish a defendant's "due care."<sup>40</sup> Other states have statutes that bar punitive damages awards against manufacturers complying with FDA requirements.<sup>41</sup>

Courts have generally refused to apply the statutory compliance defense for FDA-regulated products. Juries have overridden the scientific determination of the FDA and found government-mandated warnings to be inadequate, thereby causing manufacturers to change their labeling.<sup>42</sup> For instance, in MacDonald v. Ortho Pharmaceutical Corp.,<sup>43</sup> the Massachusetts Supreme Judicial Court upheld a verdict for the plaintiff, and held that an FDA warning on an oral contraceptive drug was inadequate even though the manufacturer had furnished a detailed description of the drug's risk of abnormal clotting associated with the use of the pill.<sup>44</sup> Courts have also imposed liability on manufacturers even where the FDA said that a warning was

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The Restatement (Third) of Torts: Products Liability, states: "Compliance with a safety statute is relevant and admissible with regard to whether the defendant met the applicable tort standard of care, but is not dispositive." Restatement (Third) of Torts: Products Liability, section 7(b) (Tentative Draft No. 2, 1995).

<sup>40</sup>See Warren, *supra* note 34, at 781-782. For example, the Tennessee Products Liability Act of 1978 states the following: "Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards." TENN. CODE. ANN. § 29-28-104 (1980 & Supp. 1995); *see also* MICH. STAT. ANN. § 27A.2946(5) (Law. Co-op 1996) (tort actions against drug manufacturers complying with FDA regulations are allowed only if the company has intentionally withheld or misrepresented information to the FDA, or bribed FDA officials.) *Compare with* WASH. REV. CODE. ANN. § 7.72.050(1)(1992), which states, "Evidence... that the product was or was not, in compliance... with legislative regulatory standards or administrative regulatory standards, whether relating to design, construction or performance of the product or to warnings or instructions as to its use may be considered by the trier of fact." *Id.*

<sup>41</sup>*See, e.g.*, N.J. STAT. ANN. § 2A:58C-5(c) (1987); OHIO REV. CODE. ANN. § 2307.80 (1988); OR. REV. STAT. § 30.927 (1987). The U.S. House of Representatives also passed a bill which would bar punitive damages for manufacturers complying with FDA regulations, but would allow awards in cases of intentional failure to report or in cases of bribery. *See* H.R. 956, § 201(f), 104<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1995); *see also* *Hearings on S. 1400 Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 101<sup>st</sup> Cong., 315 (1997).

<sup>42</sup>*See* John F. Del Giorno, *Federal Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629, 630 (1989).

<sup>43</sup>*MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985).

<sup>44</sup>*See id.* at 67, n. 4. The FDA regulations labeled the pill with a warning that "oral contraceptives are powerful and effective drugs that can cause side effects in some users and should not be used at all by some women," and that "[t]he most serious known side effect is abnormal blood clotting that can be fatal." *Id.* at 66 & n. 3 (quoting 35 Fed. Reg. 9002-9003 (1970)). The warning did not use the word "stroke" in describing the abnormal blood clotting. The plaintiff suffered a stroke as a result of taking the pill and was allowed to recover. *See id.* at 70-71. The court said the warning was inadequate because it was not "comprehensible to the average consumer" or because it should have warned of both the risk of permanent disability as well as death. *Id.* at 71-72; After the plaintiff's injury, but prior to trial, the FDA revised the warning to require that the label warn of strokes. *See id.* at 67, n. 6 (citing 43 Fed. Reg. 4221 (1978)); *see also* Frederick C. Schafrick, *Product Liability Suits For Failure to Warn of the Hazards of Regulated Products*, 32 TORT & INS. L. J. 833 (1997) (pages not available).



unnecessary.<sup>45</sup> For example, the 11<sup>th</sup> Circuit held a defendant liable when it deferred to an FDA determination that it need not include an unsubstantiated warning detailing the link between spermicide and birth defects.<sup>46</sup> In another example, a Kansas court awarded \$2.75 million in punitive damages against a manufacturer who failed to warn of kidney disease, even though the FDA had explicitly rejected the request by another manufacturer to amend its labeling to warn of that precise risk.<sup>47</sup>

As a consequence of weak federal preemption and the refusal of courts to recognize a statutory compliance defense, except where granted by statute, manufacturers typically face two different types of regulation: 1) liability in tort and 2) regulation of safety standards by the FDA and/or state legislatures or agencies.<sup>48</sup> State product liability claims are divided into three parts: failure-to-warn claims, manufacturing defect claims and design defect claims.<sup>49</sup> Under most state's tort laws, manufacturers can be held liable in both negligence and strict liability for failing to warn of a product's hazards.<sup>50</sup> To safeguard themselves against liability, manufacturers generally must take reasonable measures to inform users of dangers associated with the product, usually by issuing warning labels.<sup>51</sup> Federal and state regulatory law also generally require manufacturers to warn consumers of the hazards associated with regulatory products.<sup>52</sup>

With a rise in product liability actions and increased federal and state legislative regulation, manufacturers

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<sup>45</sup> See Schafrick, *supra* note 44.

<sup>46</sup> Wells v. Ortho Pharmaceuticals, 788 F.2d 741 (11<sup>th</sup> Cir. 1985). The court found that the evidence linking spermicide and birth defects was "so insubstantial" that no warning was required. *See id.* at 746; *see also* Schafrick, *supra* note 44.

<sup>47</sup> Wooderson v. Ortho Pharmaceutical Corp., 681 P.2d 1038 (Kan. 1984).

<sup>48</sup> See Warren, *supra* note 34, at 779.

<sup>49</sup> See Page Keeton et. AL., PROSSER AND KEETON ON THE LAW OF TORTS, §99, at 685-88, §99, at 697-98 (5<sup>th</sup> ed. 1984).

<sup>50</sup> See Schafrick, *supra* note 44; Prosser, *supra* note 49, at §96. Most pharmaceutical cases involve failure-to-warn claims. *See* Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS L. J. 163, 168 (1998). Since the FDA prescribes good manufacturing processes, and since drugs cannot be designed in an alternative fashion, tort cases involving manufacturing defects or design defects are rare. *See id.* Under a negligence theory, manufacturers have a duty to exercise reasonable care to inform users of potential dangers associated with the probable uses of the product if the manufacturer 1) knows or should know of those dangers, and 2) has no reason to believe that an ordinary user will know of them. Keeton, *supra* note 49, §96, at 685. Manufacturers, however, have no duty to warn of dangers which would be obvious to an ordinary user, or dangers experts could not have reasonably foreseen. *See* Schafrick, *supra* note 44. A manufacturer's duties under strict liability are nearly the same as under negligence. However, under negligence, "one determines whether the manufacturer acted reasonably in selling the product with whatever warnings accompanied it; under strict liability, one determines whether the product was defective in light of the warnings that accompanied it." *Id.*

<sup>51</sup> See Schafrick, *supra* note 44.

<sup>52</sup> *See id.* An example is the Federal Cigarette and Advertising Act which requires cigarette packages to bear specific warnings about health hazards associated with smoking. 15 U.S.C. §§ 1331-1341 (1994).

began to call for change. The first such change came indirectly, as courts reversed direction and began to expansively construe congressional intent to preempt state requirements.<sup>53</sup> Starting in the 1980s, courts began to use the preemption language of federal consumer protection laws to extend federal preemption to state product liability laws.<sup>54</sup> In the 1992 case, Cipollone v. Liggett Group Inc.,<sup>55</sup> the Supreme Court signaled a broad use of the preemption defense to bar state product liability actions. The 1969 Cigarette Labeling Act stated, “No requirement or prohibition based on smoking and health shall be imposed under State law with respect to advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”<sup>56</sup> In interpreting the Act and writing for a plurality of four, Justice Stevens concluded that the phrase “requirement or prohibition...imposed under State law,” could refer to both positive legislative enactments and to state tort actions.<sup>57</sup> Cipollone provided a “springboard” for courts to hold consumer’s claimed preempted under other statutes.<sup>58</sup> Most significantly, courts began to construe Cipollone expansively and to apply its broad reasoning to the provisions of the MDA as preempting state tort suits dealing with medical devices.<sup>59</sup>

<sup>53</sup>See Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 Food & Drug L.J. 183, 183 (1994) (“[T]he medical device industry has benefited from a gradual evolution of case law affording even greater preemption effect to requirements of the Food and Drug Administration. To be sure, devices alone among FDA-regulated products are the subject of an express statutory preemption clause, but that cannot by itself account for the very different trajectories of preemption defenses in drug and device cases.”)

<sup>54</sup>See Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 747 (1997).

<sup>55</sup>Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992). For a detailed discussion of the case, see Carrier, *supra* note 29, at 535-547.

<sup>56</sup>Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, as amended, 15 U.S.C. §§1331-1340, at §5(b).

<sup>57</sup>Cipollone, 505 U.S. at 522.

<sup>58</sup>See Leflar, *supra* note 54, at 698.

<sup>59</sup>A proposed FDA rule stated that it was not until after Cipollone that “lower courts interpreted [the MDA]...to preempt tort actions respecting allegedly defective medical devices...based on State common law.” 62 Fed. Reg. 65385 (1997). See, e.g., King v. Collagen Corp., 983 F.2d 1130, 1134 (11<sup>th</sup> Cir. 1993) (finding that because the manufacturer had received the FDA’s premarket approval for a wrinkle cream treatment, the claim was preempted within the meaning of § 360k of the MDA); Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5<sup>th</sup> Cir. 1993) (FDA’s premarket approval process and post-approval regulatory powers preempted state liability suit); Talbott v. Bard, Inc., 63 F.3d 25, 26 (1<sup>st</sup> Cir. 1995) (Manufacturer immunized from tort liability even where manufacturer admittedly and intentionally had violated provisions of federal law to ensure safety and efficacy of medical devices). Prior to Medtronic, only one federal court held that the MDA did not preempt state tort actions. See Kennedy v. Collagen Corp., 67 F.3d 1453, 1459 (9<sup>th</sup> Cir. 1995). For a discussion of other cases in which courts have interpreted the MDA provisions of the MDA prior to Medtronic, see Gary L. Wilson, *Listen to the FDA: The Medical Device Amendments Do Not Preempt Tort Law*, 19 HAMLINE L. REV. 409 (1996) (“The Preemption Jurisprudence is a Mess.”) *Id.* at 416; Noah, *supra* note 53, at 190-200.

In 1996, the Supreme Court appeared to stop the trend of Cipollone to imply federal preemption of state tort suits.<sup>60</sup> In Medtronic v. Lohr,<sup>61</sup> the plaintiff alleged that Medtronic, the manufacturer of a cardiac pacemaker, failed to warn her physician of the device's tendency to fail in life-threatening situations, despite the manufacturer's knowledge of defects.<sup>62</sup> Medtronic claimed that the plaintiff's suit was barred by § 360k of the MDA, which states:

Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement — 1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and 2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the Act.<sup>63</sup>

The Court held that the state product liability claim over the defective pacemaker was not preempted by § 360k(a) of the MDA.<sup>64</sup> In order to be preempted, the Court reasoned, the FDA requirements must be “specific counterpart regulations... applicable to a particular device,”<sup>65</sup> and that the preempted state requirements not be “of general applicability.”<sup>66</sup> At issue in Medtronic were federal labeling requirements that required in warning labels “information for use... and any relevant hazards, contraindications, side effects, and precautions.”<sup>67</sup> The product had undergone the § 510 (k) review process in which a manufacturer notifies FDA that a device is “substantially equivalent” to an existing device, thereby bypassing FDA review of the full safety and effectiveness of the device.<sup>68</sup> For the pacemaker, preemption failed because the federal

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<sup>60</sup>Since Medtronic, Congress has been reluctant to impose sweeping federal preemption of state product liability laws. For example, the Proposed Product Liability Reform Act of 1997, S. 5, 105<sup>th</sup> Cong. (1997), would have preempted state tort law in certain ways but would have left the “core” of state civil remedies intact. See Leflar, *supra* note 54, at 748, n. 4; H.R. 956, 104<sup>th</sup> Cong. §102(b) (1996) (discussed in Cynthia C. Lebow, *Federalism and Federal Product Liability Reform: A Warning Not Heeded*, 64 TENN. L. REV. 663 (1997)). A preemption change similar to Cipollone would have “attacked the core itself, by completing foreclosing many types of claims for entire categories of regulated products.” Leflar, *supra* note 54, at 748, n. 4.

<sup>61</sup>For a detailed discussion of Medtronic, see Robert J. Katerberg, *Patching the “Crazy Quilt” of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440 (1997).

<sup>62</sup>Medtronic, 116 S.Ct. at 2248.

<sup>64</sup>Medtronic, 116 S.Ct. at 2259.

<sup>65</sup>21 C.F.R. § 808.1(d).

<sup>66</sup>21 C.F.R. § 808.1(d)(1). In order to be candidates for preemption, state requirements must be 1) developed “with respect to medical devices”; 2) specific in terms of applicability, thereby saving from preemption state requirements of “general applicability,” ; 3) “different from or in addition to ‘federal requirements’”; and 4) concerned with safety, efficacy, or any other matter included in a federal requirement that applies to the device.” Medtronic, 116 S.Ct. at 2257.

<sup>67</sup>21 C.F.R. § 801.109(c) (1996).

<sup>68</sup>Medtronic, 116 S.Ct. at 2258.

labeling and manufacturing requirements were not designed with the specific device in mind, and the state tort law duties were not device-specific.<sup>69</sup> The Court’s decision is consistent with both legislative history and FDA interpretation. The legislative history of MDA was “devoid” of any mention of state tort suits as a basis for preemption,<sup>70</sup> and the FDA had taken a “restrictive” interpretation of the preemption provision.<sup>71</sup>

### III. The Need for National Uniformity and Federal Preemption of State Product Liability Actions

Congress’ position on the preemption of state laws dealing with labeling, safety, and tort suits lacks coherence and consistency. FDAMA preempts state regulation of OTC labeling and safety standards, but only preempts state labeling requirements for cosmetics. States can fully regulate food safety standards, but the federal government exclusively regulates most food labeling. Plaintiffs currently are free to pursue products liability actions for failing-to-warn for drugs, foods, and cosmetics, but it is unclear whether there is any preemption for tort suits involving medical devices. The National Childhood Vaccination Injury Act (“NCVI”) appears

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<sup>69</sup> *Id.*

<sup>70</sup> See Leflar, *supra* note 54, at 704; see also H.Rep. No. 94-853, at 45-46 (1976). Leflar notes that the absence of any mention of preemption of state tort suits is “unsurprising,” given the fact that at the time of the MDA’s enactment, the “near-universal” rule was that compliance with regulatory standards could only constitute evidence of due care or nondefectiveness in tort actions. *Id.* at 704. Leflar also indicates that the MDA also contains a limited savings clause which indicates that preemption of state tort suits was “not part of the congressional design” in enacting the MDA. *Id.* at 706. The MDA authorizes the FDA to issue orders requiring manufacturers and distributors to notify doctors and patients about medical devices with an unreasonable risk of harm. See 21 U.S.C. §360h(a), (b) (1994), as cited in Leflar, *supra* note 54, at 706. The section continues and says, “Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law.” *Id.* at § 360h(d).

<sup>71</sup> See Leflar, *supra* note 54, at 706. 21 C.F.R. §§ 808.1(d) says that state and local requirements of general applicability are not preempted, but a state’s “substantive requirement for a specific device” might be preempted only if the FDA had established a “specific counterpart regulations or . . . other specific requirements applicable to a particular device.” *Id.* The FDA also submitted an amicus brief in *Medtronic*. The agency explained that it had consistently construed the term “requirement” to refer to substantive rather than remedial measures. See Brief for the United States as Amicus Curiae Supporting Respondents/Cross-Petitioners, *Medtronic, Inc., v. Lohr*, 116 S.Ct. 2240 (1996), Nos. 95-754, 95-886 (U.S. Mar. 13, 1996), 1996 WL 118035, at \*13; see also Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD AND DRUG L. J. 7, 10 (1997) (“The agency’s position was adopted by the Supreme Court in *Lohr*. The Court accepted FDA’s narrow construction of the scope of section 521, reasoning that a finding of broad preemption would be entirely at odds with Congress’ intent in enacting the MDA.”). For an analysis of the weight courts should give to FDA’s conclusions about the preemptive effect of the FDCA, see Amanda Frost, *Judicial Review of FDA Preemption Determinations*, 54 FOOD & DRUG L.J. 367 (1999).

to almost *require* that state law tort remedies be available to injured users of vaccines.<sup>72</sup> Is there any rationale for the disparity? Is FDA regulation so lax in some fields that states need to supplement federal safety standards, either through positive legislative enactments or state tort suits? Are there some areas in which lay juries are more competent than the FDA to place liability on manufacturers who have complied with FDA requirements? Are cigarettes<sup>73</sup> and pesticides<sup>74</sup> more worthy of preemption than FDA-regulated products?

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<sup>72</sup>See Geiger, *supra* note 33, at 406; 42 U.S.C. § 300aa-22(e). The NCVI Act does have a preemption provision which states, No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.” *Id.* Geiger argues that “the effect of the NCVI Act’s express preemption provision is to prohibit states from eliminating the applicability of their own tort and contract laws vis-à-vis victims of vaccines.” Geiger, *supra* note 33, at 406.

<sup>73</sup>See *Cipollone*, 505 U.S. 504 (1992); see *supra* p. 9-10. In *Cipollone*, the Court held that the Federal Cigarette Labeling and Advertising Act preempted a state court tort action for failing to warn of the dangers of smoking cigarettes. See also Del Giorgio, *supra* note 42, at 642. (“The court’s willingness to find a dominant national interest in the context of cigarette smoking, but not for prescription drugs, is astonishing.”)

<sup>74</sup>See The Federal Insecticide, Fungicide, and Rodenticide Act, which expressly preempts any state statutory enactment that purports to regulate labeling or packaging on pesticides. 7 U.S.C. § 136v(b) (1994). FIFRA, however, does not expressly preempt state tort law, but has been held by some courts to impliedly preempt state tort law, even though its regulations are less comprehensive than those of the FDA. See, e.g., *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10<sup>th</sup> Cir. 1992) (holding that FIFRA impliedly preempted failure-to-warn-claim). For more information on FIFRA, see, e.g., Carrier, *supra* note 29, at 600-609; Celeste Marie Steen, *FIRFA’s Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763 (1996); Stephen D. Otero, *The Case Against FIFRA Preemption: Reconciling Cipollone’s Preemption Approach with Both the Supremacy Clause and Basic Notions of Federalism*, 36 WM. & MARY L. R. 783 (1995).

Although a different regulatory regime monitors each product, all four industries – drugs, medical devices, cosmetics, and food - are undergoing changes which should mandate national uniformity for labeling and safety standards and should allow for the preemption of state product liability actions. As indicated by the legislative history of FDAMA:

Different or additional requirements at the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to public health, and result in divergent public health protection throughout the country.<sup>75</sup>

From as early as 1894, states have clamored for national uniformity in food and drug laws. In 1894, the Association of Official Agricultural Chemists wrote in its constitution that its objectives “were to secure, as far as possible, uniformity in legislation... and uniformity and accuracy in the methods and results [of analysis.]”<sup>76</sup> In 1897, representatives from ten states met to establish uniform laws.<sup>77</sup> The resulting organization – the Association of Food and Drug Officials – still has as its principal aim the establishment of uniform food and drug laws.<sup>78</sup> Congress has also tried but failed to establish national uniformity. In 1988, a bill was introduced in the Senate to mandate national uniformity in all aspects of the regulation of food for human use, drugs, medical devices and cosmetics.<sup>79</sup> In 1991, the Edwards Committee called for the “national uniformity” of all products regulated by the FDA, with states being able to seek preemption with convincing local circumstances.<sup>80</sup> Indeed, the Committee felt that national uniformity was so necessary that it recommended that if Congress had not enacted such legislation by the close of session of the 102nd Congress, the FDA should issue regulations accomplishing the same goals.<sup>81</sup>

National uniformity will have added benefits to both consumers and to manufacturers. There are generally

four areas of food and drug regulation: 1) environmental sanitation; 2) safety standards; 3) economic reg-

<sup>75</sup>S. Rep. No. 105-43, at 63-67 (1997), as reprinted in *An Analytical Legislative History of FDAMA* (McKenna & Cuneo, ed. 1998), at 344.

ulation; and 4) composition and standardization.<sup>82</sup> H. Thomas Austern argues that while states may be best as safeguarding environmental sanitation, the federal government is more effective at regulating safety standards, and in ensuring the highest degree of economic regulation.<sup>83</sup> States do not have the resources to adequately test products, and economies of scale dictate that the free movement of goods is best accomplished by uniform standards and labeling.<sup>84</sup> Austern also argues that while the issue of whether the states or the federal government should establish standardization is “the most discomforting area of chaos and perhaps plain rivalry,” the decision should tilt in favor of the federal government, provided it develops more responsive mechanisms for consideration and consultation of state views.<sup>85</sup> FDAMA, for instance, does just that, by providing exemption provisions which allow individual states to petition the FDA to make a state idea a national requirement if circumstances warrant; FDAMA also has provisions allowing states to act in emergency situations.<sup>86</sup>

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the FDA or the state had obtained an exemption; As Westerfield notes, “The failure of [Title VII] to even reach the Senate bill exemplifies a congressional uneasiness with permitting a federal agency to override state law, particularly in the area of the health and safety of citizens.” Westerfield, *supra* note 31, at 281.

<sup>80</sup>See Department of Health and Human Servs., Final Report of the Advisory Committee on Food and Drug Administration 50 (1991); see also Mark B. Gelbert, State Statutes Affecting the Labeling of OTC Drugs: Constitutionality Based on Commerce Clause and Federal Preemption Theories, 46 Food, Drug & Cosm. J. 629, 661 (1991); 143 Cong. rec. S8890 (Sept. 8, 1997) (statement of Sen. Gregg).

<sup>81</sup>See Department of Health and Human Servs., Final Report of the Advisory Committee on the Food and Drug Administration; see also Gelbert, *supra* note 80, at 661.

<sup>82</sup>See H. Thomas Austern, *Federalism In Consumer Protection: Conflict or Coordination?*, 29 BULLETIN OF THE ASS’N OF FOOD AND DRUG OFFICIALS OF THE U.S., No. 4, at 148 (1965), in HUTT & MERRILL, *supra* note 75, at 992-993.

<sup>83</sup>*See id.*

<sup>84</sup>*See id.*

<sup>85</sup>*Id.* As Austern writes, “It is not too much to hope that in this area of economic control over composition of food products, the States will yield to Federal standardization, and at the same time that the FDA will develop better and more responsive mechanisms for consultation and consideration of the views of State officials...” *Id.*

<sup>86</sup>21 U.S.C. § 379(r); FDAMA § 412(a); FDCA § 751; 21 U.S.C. 379(s); FDAMA § 412(d); FDCA § 752(b).

National uniformity assures consumers that one federal agency will monitor the safety of its products for all citizens. National uniformity needs to be adopted to level out the playing field. As Senator Jeffords said during the congressional debates on FDAMA, small states often do not have the resources to conduct comprehensive testing of products and to pass legislature in response to damaging results.<sup>87</sup> Since “[i]f a food, drug, or cosmetic is safe in one state, it is safe in all states,”<sup>88</sup> there appears to be no rationale for allowing large states to protect their citizens more than smaller states. The FDA is in a much better position than the individual states to measure the safety and efficacy of products, as it is simply a waste of resources to have 51 different regulatory agencies doing the same work as the FDA.<sup>89</sup> National uniformity is also needed to ensure that safety – rather than politics – governs regulation. Regulation of foods, drugs, and cosmetics has been an “attractive target” for local legislators to appeal to local industries and to protect local markets.<sup>90</sup> In fact, states often regulate the environment under the guise of cosmetics regulation.<sup>91</sup>

Yet, at the same time, Congress should recognize that if the United States truly wishes to reap the benefits derived from national uniformity, it must resolve the inconsistency that currently exists by the allowance of tort suits. Requiring national uniformity is akin to a “federal dictate,”<sup>92</sup> and FDAMA, by simultaneously re-

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<sup>87</sup>143 Cong. rec.S8894 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>88</sup>Hearings on H.R. 3200 Food Amendments and the Animal Drug Availability Act of 1996 Before the Subcommittee on Health and the Environment, 103rd Cong. (May 1, 1996) (statement of Peter Barton Hutt on behalf of the Grocery Manufacturers Association of America and the Cosmetic, Toiletry, and Fragrance Association).

<sup>89</sup>See Gelbert, *supra* note 80, at 658.

<sup>90</sup>Hearings on H.R. 3200 Food Amendments and the Animal Drug Availability Act of 1996 Before the Subcommittee on Health and the Environment, 103rd Cong. (May 1, 1996) (statement of Peter Barton Hutt on behalf of the Grocery Manufacturers Association of America and the Cosmetic, Toiletry, and Fragrance Association).

<sup>91</sup>See *infra* pp. 48-50.

<sup>92</sup>Leflar, *supra* note 54, at 713. “A federal dictate... necessarily carries with it the implication that the aspect of the product to which the dictate refers is in compliance with the law, and that any variance is not to be tolerated. A contrary state-law jury finding would be incompatible with the Supremacy Clause.” *Id.*



quiring national uniformity while allowing state tort actions to proceed, is forcing manufacturers into a catch 22 – a “regulatory compliance trap” in which noncompliance with federal regulations creates a presumption of negligence, but compliance would not negate liability.<sup>93</sup> In the past, where the FDA has mandated uniform labeling standards, courts have sometimes preempted state tort actions seeking to impose higher standards on manufacturers.<sup>94</sup> The FDA’s regulation of tampons provides the most vivid example. FDA regulations specify that tampon labels must contain information relating to tampon absorbency and the risk of toxic shock syndrome.<sup>95</sup> Courts addressing failure-to-warn claims of tampons have held that failure-to-warn claims alleging defective labeling are preempted by compliance with these FDA regulations.<sup>96</sup> Now, with the explicit disallowance of state tort suits for cosmetics and OTC drugs,<sup>97</sup> courts will no longer have the luxury to resolve the inconsistency on their own by allowing strict FDA regulations to preempt state standards. Consequently, allowing the jury to determine that a federally-approved and nationally uniform warning is inadequate – which is what happens when juries rule in favor of plaintiffs – stands “as an obstacle to the accomplishment and execution of the full objectives of Congress in its regulation of labeling.”<sup>98</sup> Benefits gained from national uniformity will be compromised by tort suits. Uniform labeling will directly conflict with the manufacturer’s desire to include more information to deflect tort suits on failure-to-warn. Large damage awards contradict the low prices occurring as a result of less burdened regulation by the states.

The pressing need for the globalization of food, drug, and cosmetic regulation adds to the tension. Globalization of the pharmaceutical, cosmetic, and food industries makes national uniformity almost inevitable.<sup>99</sup>

<sup>93</sup>Thomas M. Moore & Siobhan A. Cullen, *Impact of Global Pharmaceutical Regulations on U.S. Products Liability Exposure*, 66 DEF. COUNS. J. 101, 101 (1999).

<sup>94</sup>See Leflar, *supra* note 54, at 731-732.

<sup>95</sup>21 C.F.R. § 801.430.

<sup>96</sup>See, e.g., *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8<sup>th</sup> Cir. 1994) (failure-to-warn claim preempted; testing, design, and manufacturing claims permitted); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5<sup>th</sup> Cir. 1989) (same).

<sup>97</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(e); 21 C.F.R. § 379s; FDAMA § 412(a); FDCA § 752(d); see *supra* footnote 14.

<sup>98</sup>Jennie Clarke, *Federal Preemption: A Vaccine Manufacturer’s Defense*, 56 MO. L. REV. 515, 536 (1988).

<sup>99</sup>As Peter Barton Hutt said, “National uniformity – which requires internal harmonization of our own laws and regulations – is an integral part of international harmonization.” *Hearings on H.R. 3200 Food Amendments and the Animal Drug Avail-*

The mounting trend toward globalization will force nations to alter their existing regulatory regimes.<sup>100</sup> For instance, the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use represents an attempt to harmonize the scientific requirements of the pharmaceutical regulatory agencies in the United States, Japan, and Europe “in order to speed up the time from developing to marketing of new drugs.”<sup>101</sup> The Codex Alimentarius Commission has pursued a similar effort for the food industry.<sup>102</sup> FDAMA also adopted this spirit of global harmonization. Section 410 of FDAMA declares that the FDA should support the negotiation of mutual recognition agreements on international regulatory harmonization regarding drugs, biological products, devices, foods, food additives, color additives, and good manufacturing processes if participation would be consistent with the FDA’s goal of consumer protection.<sup>103</sup> The increased globalization of standards, product development, and marketing has sparked a “new and potentially dangerous twist to the regulatory compliance trap.”<sup>104</sup> Globalization increases the number of regulatory regimes manufacturers are subject to. Consequently, the products liability exposure of U.S. corporations increases, since plaintiffs’ counsel often point to differences in product design and labeling on U.S. products in foreign countries as evidence of “defectiveness” in products sold in the United States.<sup>105</sup> Inquiries by foreign agencies can also be used as evidence of liability or causation in torts suits.<sup>106</sup> Increased exposure to products liability suits is only exacerbated by the fact that an increasing number of pharmaceu-

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*ability Act of 1996 Before the Subcommittee on Health and the Environment*, 103<sup>rd</sup> Cong. (May 1, 1996) (statement of Peter Barton Hutt on behalf of the Grocery Manufacturers Association of America and the Cosmetic, Toiletry, and Fragrance Association); *see also* Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 693 (1998) (“[Globalization] trends have compelled FDA, as well as the industries it regulates, . . . to rethink their international strategy.”)

<sup>100</sup>*See* John S. Eldred & Shirley A. Coffield, *What Every Food Manufacturer Needs to Know: Realizing the Impact of Globalization on National Food Regulation*, 52 FOOD & DRUG L.J. 31, 37 (1997).

<sup>101</sup>Moore, *supra* note 93, at 107; *see also* Horton, *supra* note 99.

<sup>102</sup>*See* Eldred & Coffield, *supra* note 102. The Codex has 151 member countries and is a subsidiary body of two United Nations organizations, the World Health Organization, and the Food and Agriculture Organization. *See id.* at 31-32. “The Codex develops a model international approach to food legislation, but does not require harmonization.” *Id.* at 33; *see also* Marsha A. Echols, *Food Safety Regulations in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. L. EUR. L. 525 (1998); Linda R. Horton, *International Harmonization of Food and Veterinary Medicine Products*, in *THE FUNDAMENTALS OF LAW AND REGULATION* 381-484 (Robert E. Brady et al. ed. 1997).

<sup>103</sup>21 U.S.C. § 383; FDAMA § 410.

<sup>104</sup>Moore, *supra* note 93, at 101. For a discussion of the drug approval process in both the European Union and Japan, *see id.* at 102-105.

<sup>105</sup>*See id.* at 102.

<sup>106</sup>*See id.*

tical, medical device, and cosmetics companies are owned outside the United States; these companies may also have subsidiaries worldwide.<sup>107</sup>

The FDA is now at a crossroads. Faced with the benefits derived from national uniformity of product regulation and an increased pressure to harmonize standards internationally, FDAMA represents a needed first step to achieving these goals. The question remains, however, whether only some FDA-regulated products should enjoy national uniformity. The premise of this paper is that all of the products regulated by the FDA should share equally in benefiting from national uniformity provisions. A second question arises when one ponders whether national uniformity should only apply to positive state legislative enactments or whether it should also apply to the more indirect way states regulate through tort law. The argument in this paper is that the benefits of national uniformity derived by preempting positive legislative enactments will be compromised by allowing states to continue to regulate through their judicial system. The following sections will address each FDA-regulated product in turn to explain why preemption of both positive legislative enactments and state tort law should be granted.

## IV. DRUGS

### A.

#### History of Drug Regulation

The Pure Food and Drug Act of 1906<sup>108</sup> was Congress' first successful attempt to regulate the ever-growing national scope of the nation's food and drug supply. The original act banned the manufacture and distribution

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<sup>107</sup>*See id.* at 106.

<sup>108</sup>Pub. L. No. 59-384, 34 Stat. 768 (1906).

of adulterated<sup>109</sup> and misbranded food and drugs;<sup>110</sup> it also forbid false and misleading labeling of foods and drugs concerning the identity and composition of the product.<sup>111</sup> The 1906 Act, however, was notably weak. The Act did not extend its coverage to cosmetics or medical devices, and it did not provide for premarket testing for drug safety.<sup>112</sup> In order to be subject to the Act's seizure or criminal penalties, potential violators had to place an adulterated or misbranded item into interstate commerce.<sup>113</sup> The Act also did not create liability for false statements about the therapeutic effects of a drug.<sup>114</sup>

The rise of the post-New Deal administrative state and frightening drug scares prompted Congress to dramatically strengthen the powers of the FDA under the 1906 Act. The death of over one hundred people who took the drug Elixir Sulfanilamide prompted the FDA to include in the 1938 Food, Drug, and Cosmetic Act ("FDCA") safety reviews of drugs before entering commercial distribution.<sup>115</sup> FDA enforcement powers were also enhanced. In 1962, Congress acted to dramatically change the drug approval process. The 1962 Kefauver-Harris Amendments required the FDA to ensure that a drug was both safe and effective for the purposes it was intended to be used.<sup>116</sup> Congress also expanded the reach of FDA authority, as the amendments required pharmaceutical manufacturers to get FDA approval to both market a drug and to begin

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<sup>109</sup>21 U.S.C. § 331(a); FDCA § 301(a). The federal FDCA prohibits the introduction or delivery for introduction into interstate commerce any drug or device that is adulterated. *Id.* The Act defines adulterated drugs and devices to include those that did not proceed through the appropriate premarket regulatory process. See 21 U.S.C. § 351(a)(2)(B).

<sup>110</sup>21 U.S.C. § 352(j); FDCA § 502. A drug is deemed misbranded if "it is dangerous to health when used. . . with the frequency or duration prescribed, recommended or suggested in the labeling."

<sup>111</sup>21 U.S.C. § 352(a); FDCA § 502(a). A drug is misbranded under the FDCA if it fails to bear the statements required by the FDCA or its labeling is false or misleading "in any particular." The government has the burden to establish that a label is false or misleading – it need not "conscious fraud" motivated the wording on the label. *United States v. Articles of Drug . . . Colchicine*, 442 F. Supp. 1236, 1241 (S.D.N.Y. 1978). See also Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 890 (1996).

<sup>112</sup>See Walsh, *supra* note 111, at 890.

<sup>113</sup>See *id.* 21 U.S.C. § 331(a); FDCA § 301(a).

<sup>114</sup>See Walsh, *supra* note 111, at 890.

<sup>115</sup>The primary purpose of the FDCA was to protect the health and safety of the public by preventing deleterious, adulterated, or misbranded articles from entering interstate commerce. See Erica L. Niezgoda & Maureen M. Richardson, *Federal Food and Drug Act Violations*, 35 AM. CRIM. L. REV. 767, 767 (1998).

<sup>116</sup>21 U.S.C. § 321(p)(2).

clinical testing.<sup>117</sup>

In 1951, the Durham-Humphrey Amendments<sup>118</sup> to FDCA codified FDA regulations that developed a classified system for drugs: drugs that could not be used without medical supervision (prescription drugs), and drugs which could be marketed over-the-counter.<sup>119</sup> In 1972, FDA began the process of reviewing all OTC drugs on the market, a market where there were approximately 500,000 OTC drug products comprising 200 different active ingredients.<sup>120</sup> Rather than review the safety and efficacy of each individual drug, the FDA took the approach of studying “active ingredients” and classifying drugs into categories.<sup>121</sup>

The 1962 Amendments granted the FDA new powers. The FDA could now regulate drug advertising and promotional activities.<sup>122</sup> FDA officials could inspect drug manufacturing facilities and promulgate regulations governing good manufacturing practices for drugs.<sup>123</sup> The 1962 Amendments also signaled the “FDA’s first attempt at post-market surveillance of drugs for safety,” as drug manufacturers had to notify the FDA of adverse reactions to pharmaceuticals.<sup>124</sup> The 1962 amendments mandated that OTC drugs meet the FDA’s effectiveness standards for new drugs, including those approved from 1938-1962.<sup>125</sup>

The FDA also specifies requirements for drug labeling. FDA regulations require that labels on drugs not be false or misleading, that they bear adequate directions for use, and contain warnings against unsafe use,

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<sup>117</sup>21 U.S.C. § 321(p); FDCA § 355. Review of safety data applied both to new drugs and to drugs approved by the FDA prior to the amendments. In order to handle the workload, the FDA contracted with the National Academy of Science-National Research Council, which recommended efficacy classifications over which the FDA exercised great deference. *See* Walsh, *supra* note 111, at 899.

<sup>118</sup>Pub. L. No. 82-215, 65 Stat. 648 (1951); *see also* James F. Hoge, The Durham-Humphrey Bill, 6 FOOD DRUG COSM. L. J. 135 (1951).

<sup>119</sup>The amendments said that a drug may only be dispensed for prescription use if 1) it is habit forming; 2) because of its toxicity... it is not safe for use except under supervision; and 3) it is limited to prescription use by an approved application. 21 U.S.C. § 353(b). For an overview of the history of OTC drug regulation, *see* Stan Stringer, *What Has Been Happening with Over-The-Counter Drug Regulation*, 53 FOOD & DRUG L. J. 663 (1998).

<sup>120</sup>*See* Gelbert, *supra* note 80, at 631-632.

<sup>121</sup>*See id.*

<sup>122</sup>21 U.S.C. § 301; FDCA § 392.

<sup>123</sup>21 U.S.C. § 351(a)(2)(B); FDCA § 501(a)(2)(B). A drug is deemed adulterated if the facilities, controls, and manufacturing, processing, packing and storage methods under which it is produced to good manufacturing processes.

<sup>124</sup>*See* Walsh, *supra* note 111, at 902.

<sup>125</sup>*See id.* at 902.

side effects, and adverse reactions.<sup>126</sup> The FDA employs a risk-benefit analysis in writing labels, and only warns consumers of adverse reactions if there is “significant medical evidence of a possible health hazard.”<sup>127</sup> The FDA does not warn consumers of adverse reactions where differences of opinions within the medical community exist.<sup>128</sup> In recent years, OTC drugs have surged, fueled by prescription to OTC drug switches, making the need for accurate and complete labeling ever more present.<sup>129</sup> As Representative Waxman stated, “[n]owhere is the need for information greater than when consumers act as their own doctors and nurses... The significance of the OTC industry’s communications with consumers, and the scrutiny they currently receive, will only increase...”<sup>130</sup>

### ***B. State Regulations of Drugs***

Despite extensive FDA regulation of OTC drugs, states have taken on a greater role in issuing legislation that is more protective than federal legislation. States have attempted to require certain language and label warnings on OTC drugs that “add additional, inconsistent, and confusing precautions to these labels, in addition to the lengthy and comprehensive labeling requirements imposed by the FDA.”<sup>131</sup> In fact, the Nonprescription Drug Manufacturers Association has stated that almost every state legislature has proposed statutes that would conflict with FDA regulations.<sup>132</sup> Examples abound. In 1993, three states sought to require bittering agents in certain OTC medicines to deter childhood poisonings and overdoses. However, Congress rejected this solution, and said that child resistant packaging and consumer education were a

<sup>126</sup>21 U.S.C. § 352(a); 21 C.F.R. § 201.6. See Gelbert, *supra* note 80, at 634-635.

<sup>127</sup>Rissier, *supra* note 13, at 1391.

<sup>128</sup>See *id.*

<sup>129</sup>See Daniel W. Whitney, *Product Liability Issues for the Expanding OTC Drug Category*, 48 FOOD & DRUG L. J. 321 (1993).

<sup>130</sup>H.A. Waxman, Self-Care: The Legislative Perspective: Remarks at the FDA’s and the Proprietary Association’s seminar, “Self-Care/Self-Medication in America’s Future,” Washington D.C. (Feb. 8, 1988), as cited in Gelbert, *supra* note 80, at 634.

<sup>131</sup>143 CONG. REC. S9846 (Sept. 24, 1997) (Attachment: Examples of State Proposals That Would Disrupt National Uniformity).

<sup>132</sup>See Nonprescription Drug Manufacturer’s Association, *National Regulatory Uniformity* (visited March 6, 2000) <<http://ndmainfo.org/facts/factsFrame.html>>.

better means to address the problem.<sup>133</sup> In the 1990s, at least 15 states considered legislation requiring “environmentally-friendly packaging” of OTC drugs.<sup>134</sup> Such regulation, however, would have directly conflicted with the FDA’s safety requirements that certain drugs be packaged only in “virgin” materials to prevent adulteration.<sup>135</sup>

The FDA has made some attempt to combat the problem of increased state regulation by issuing federal regulations that explicitly preempt state product warning labels on certain OTC drugs. The FDA included specific preemption provisions in their regulation of tampering and pregnancy warnings on OTC drugs.<sup>136</sup> In response to a rise in product tamperings, the FDA issued a Final Rule on Tamper-Resistant Packaging Requirements for Over-the-Counter Human Drug and Cosmetic Products, which required that most OTC products for retail sale be packaged in tamper-resistant packages.<sup>137</sup> The TRP rule also explicitly preempted state and local packaging requirements not identical to the federal regulations.<sup>138</sup> In 1982, the FDA followed the lead of California and required a pregnancy warning on all OTC drugs, which stated, “As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.”<sup>139</sup> In order to eliminate confusion and to create, “clear, unambiguous, and consistent” information, state requirements regarding pregnancy warnings were preempted.<sup>140</sup>

### ***C. Enactment of FDAMA***

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<sup>133</sup>143 CONG. REC. S9846 (Sept. 24, 1997) (Attachment: Examples of State Proposals That Would Disrupt National Uniformity).

<sup>134</sup>*See id.*

<sup>135</sup>*See id.*

<sup>136</sup>*See* Biana I. Truitt, *Injured Consumers and the FDA*, 15 J. LEGAL MED. 170-172 (1994).

<sup>137</sup>The regulation stated that the “FDA intends that the regulations issued in this document preempt State and local packaging requirements that are not identical to it with respect to oral and rectal OTC aspirin-containing drug products for human use.” 21 C.F.R. § 211.132.

<sup>138</sup>*See id.*

<sup>139</sup>21 C.F.R. §§ 201.63(a), 330.2.

<sup>140</sup>*Id.*

Congress responded to the increased state regulation of drugs by enacting § 412(a) of FDAMA.<sup>141</sup> FDAMA preempts state requirements dealing with the safety and labeling of OTC drugs, including requirements imposed on product manufacture or composition, advertising, or any other form of public notification or communication.<sup>142</sup> States, however, retain significant powers. Most significantly, states retain the power to enforce additional standards through state product liability suits.<sup>143</sup> While forms of public notification or communication must be identical to federal requirements, states may issue their own state warnings about OTC drugs.<sup>144</sup> States retain their enforcement authority to take immediate action against an OTC drug that was adulterated, or misbranded, and may use compliance powers identical to or different from federal mechanisms.<sup>145</sup> Under FDAMA, states would also retain the power to take action in an emergency situation without consultation by the FDA, such as for a local outbreak, and may place a drug on prescription-only status.<sup>146</sup> FDAMA also explicitly authorizes states to petition for exemptions where a local requirement may protect a public interest, the local requirement would not cause the OTC drug to be in violation of federal law, and the local requirement would not unduly burden interstate commerce.<sup>147</sup> States can also petition the FDA to make a state requirement a national one.<sup>148</sup>

#### *D. The Need for National Uniformity for Drugs*

FDAMA is a needed step in the right direction. The FDA suffers under two competing pressures. As stated

<sup>141</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(a).

<sup>142</sup>*Id.*; see also S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344.

<sup>143</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(e).

<sup>144</sup>See S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 345.

<sup>145</sup>See S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344. For instance, states may order an embargo or recall or impose civil penalties. See *id.*

<sup>146</sup>See S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344.

<sup>147</sup>21 U.S.C. § 379r; FDAMA § 412(a); FDCA § 751(b); see also S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 345.

<sup>148</sup>See S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 345.



by former FDA Commissioner David Kessler:

On analysis, it is important to recognize that the FDA could easily accelerate the availability of new drugs. Likewise, it could provide greater assurances that drugs reaching the market are safe and effective. Neither goal alone is sufficient, however. The agency's job is to balance the need to make drugs available quickly with the need to ensure that patients do not receive unsafe or ineffective products. Since it cannot pursue any single objective, criticism can always be leveled against the FDA from either direction.<sup>149</sup>

National uniformity and the allowance of state tort suits force the FDA to go in two different directions.

National uniformity seeks to ensure that state regulations do not unduly burden interstate commerce so as to decrease the speed and incentive for pharmaceutical manufacturers to develop new drugs. The goal of tort suits is to increase the safety of drugs, provide compensation to injured plaintiffs, and to make manufacturers more responsive to safety needs.<sup>150</sup> These tort goals, however, are often accomplished at the cost of discouraging speedy innovation.<sup>151</sup> Which way should the FDA go?

The benefits gained from national uniformity – lower cost drugs available to a greater number of consumers – are compromised by requiring pharmaceutical companies who comply with FDA regulations to defend themselves in tort suits. A recent FDA regulation mandating uniform OTC drug labeling represents the most vivid example of the FDA's attempt to both pursue national uniformity while at the same time force manufacturers to adhere to higher safety standards imposed by state court juries. In order to fulfill the mandate occasioned by FDAMA, in 1998, the FDA issued a proposed rule which would create a uniform federal standard for OTC labeling.<sup>152</sup> The new label would eliminate the small type and clutter common

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<sup>149</sup>*Id.* “We simply do not know how to rearrange the electrons or move the relative position of, say, the carbon and hydrogen molecules so as to squeeze out the drug's tendency to cause nausea or cell mutation, while retaining its beneficial physiological effects. Thus, the regulatory overseer cannot, as with an automobile or industrial machine, specify certain minimum standards for safety design...that might be characterized as a safety floor. Rather, with nonmodifiable drugs, the FDA must decide whether the therapeutic benefits of a new pharmaceutical outweigh the risks it poses through adverse side effects.” *Id.* at 474-475.

<sup>151</sup>*See* Schafrick, *supra* note 44. (“There is growing evidence that the present product liability system positively deters manufacturers from researching and developing innovative new products when those products will probably not generate substantial profits and could lead to substantial product liability claims.”)

<sup>152</sup>21 C.F.R. § 201.66 (1998). The rule states, “This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with this section, the content and format requirements in this section must be followed unless otherwise specifically provided in the applicable monograph or regulation.” *Id.*

among current labeling and would highlight significant warnings.<sup>153</sup> The rule, following the language of FDAMA, explicitly states that state tort suits are not preempted.<sup>154</sup> The FDA created this exception, “because there may be situations in which information about the potential harm from an OTC drug product may not be available to the FDA until after an individual consumer may have been harmed, the agency does not want to preclude compensation through tort actions in all cases related to OTC drug labeling.”<sup>155</sup>

The uniform labeling rule, however, has the effect of uprooting the scientific determinations of the FDA as to what constitutes appropriate labeling. As one commentator has noted, “A jury determination that a label is inadequate would directly conflict with the FDA determination that the label is adequate.”<sup>156</sup> Is there any justifiable rationale for a jury to conclude that FDA labels on drugs are not adequate to safeguard the highest degree of safety? Further, applied to state labeling or safety standards, is there any reason that FDA determinations should be modified by state legislation?

Given that the FDA drug approval system has such a superior safety regard, neither the FDA nor the states can do more to increase the safety of the drug supply. FDA regulation of drugs is so comprehensive that state regulation is duplicative and unneeded.<sup>157</sup> Since the FDA is a “national expert agency,” and its OTC Drug Review process is “unrivaled in the world,” there appears to be “no constitutional or policy reason to

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<sup>153</sup>The Rule proposed five changes: 1) establishing a standard for the order in which label information appears, headings and subheadings, the type style and size used on a label, the amount of space between lines of text, the use of upper- and lower-case letters, and graphical highlights; 2) allowing, but not requiring, manufacturers, packers, and distributors of over-the-counter products to eliminate certain connecting terms, including ‘and,’ ‘due to,’ ‘such as,’ or ‘while taking this product,’ to fit more information into the new format provided their omission would not change the meaning of the label information; 3) expanding the list of interchangeable terms defined in current regulations to give manufacturers and distributors more flexibility to use simpler, more understandable words on labels; 4) revising requirements for warnings on over-the-counter labels so these statements are more concise and easily understood; and 5) preempting state and local laws imposing different or additional requirements for the contents and format of OTC drug labels. 62 Fed. Reg. 9025 (1997).

<sup>154</sup>62 Fed. Reg. 9024, 9024 (1997). “This proposal would preempt State and local rules that establish different or additional format or content requirements.” *Id.*

<sup>155</sup>62 Fed. Reg. 9024, 9041 (1997). “The FDA does not want to preclude compensation through tort actions in all cases related to OTC drug product labeling.” *Id.*

<sup>156</sup>Whitney, *supra* note 129, at 349.

<sup>157</sup>Courts have also recognized the comprehensiveness of FDA regulations. *See* *Abbot v. American Cyanamid*, 844 F.2d 1108, 1112 (4<sup>th</sup> Cir. 1993) (“FDA’s regulation of prescription drugs and biological products is comprehensive... encompass[ing] the licensing, production, testing, distribution, labeling, review, and approval of all drugs and biologics.”); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1490 (D. Kan. 1987) (“The FDA’s regulation of prescription drugs is indeed far-reaching, if not pervasive.”)

prefer ‘50 mini-FDAs’ over a single national one.”<sup>158</sup> OTC drugs, in particular, are required to “have an especially wide margin of safety precisely because they are intended to be purchased and used by consumers without the intervention of a doctor.”<sup>159</sup> Like OTC drugs, prescription drugs are also subject to the “most far reaching and pervasive regulations for prescription drugs in the world.”<sup>160</sup> In fact, the FDA has been criticized more for being overly cautious in approving new drugs than in being underprotective.<sup>161</sup> The FDA is much more deficient in ensuring a speedy delivery of drugs to market than in ensuring safety.<sup>162</sup> The superior safety record of the drug supply is borne out by the low number of tort suits against the pharmaceutical industry. Indeed, studies indicate that adverse drug reactions are responsible for less than half of one percent of deaths of all hospitalized patients – and many of those deaths are attributed to human error rather than to preventable actions on the part of the pharmaceutical industry.<sup>163</sup>

Since drug safety is optimal, there appears to be no reason to allow the states to impose additional regulations, regulations which have the secondary effects of driving up costs and confusing consumers. The lack of uniformity of inconsistent and different state requirements for testing, labeling, and packaging drives up costs – costs which ultimately result in higher drug prices.<sup>164</sup> It is not “practical, efficient, or cost effective” for pharmaceutical companies to comply with, develop, manufacture, and market OTC drugs with 51 different sets of regulations.<sup>165</sup> Further, since the federal government is the financier of medical costs through

<sup>158</sup>143 CONG. REC. S9846 (Sept. 24, 1997) (statement of Sen. Jeffords).

<sup>159</sup>*Id.*

<sup>160</sup>Del Giorno, *supra* note 42, at 645.

<sup>161</sup>See Green, *supra* note 50, at 164; see also Sam Peltzman, *An Evaluation of Consumer Product Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049 (1973).

<sup>162</sup>See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1838-1839 (1996); see also Green, *supra* note 50, at 164. (“Current reform proposals focus not on the need for greater consumer protection but on the need to accelerate the approval of new drugs so that the public can gain from their therapeutic benefits.”)

<sup>163</sup>See Green, *supra* note 50, at 190, n. 20. The base against which to measure the incidence of tort suits is 2 billion prescriptions, 60,000 reported adverse reactions yearly. See Judith P. Swazey, *Prescription Drug Safety and Product Liability*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY ON SAFETY AND INNOVATION 291, 326 (Peter W. Huber & Robert E. Litan, eds., 1991); see also Donald C. Classen, et al., *Adverse Drug Events in Hospitalized Patients: Excess Length of Stay, Extra Costs, and Attributable Morality*, 277 JAMA 301, 301 (1997) (noting that adverse drug reports for hospitalized patients were accountable for 31% of deaths of hospitalized patients, many of which included incidents of the administration of the wrong drug), cited in Green, *supra* note 50, at 190, n. 20.

<sup>164</sup>143 CONG. REC. S9846 (Sept. 24, 1997) (statement of Sen. Jeffords).

<sup>165</sup>Gelbert, *supra* note 80, at 658.

Medicare and Medicaid, the federal government also has a real interest in determining whether states can burden interstate commerce by imposing different requirements on pharmaceuticals.<sup>166</sup>

Uniformity is also needed to ensure that patients receive accurate and complete information. Adverse state court decisions force pharmaceutical companies to change their warning labels.<sup>167</sup> Inclusion of additional warnings overloads the package insert with warnings, many of which may be highly conjectual.<sup>168</sup> As Schafrick notes, “Plaintiffs’ lawyers are, quite properly, concerned with those contentions that will win their individual cases, and not with what labeling will be most effective for users overall.”<sup>169</sup> Tort liability and government regulation can result in two different types of labels. Labels which arise out of tort litigation may cause the manufacturer to exaggerate the hazard and warn consumers of scientifically unproven or remotely possible dangers of a product.<sup>170</sup> For instance, in O’Gilvie v. International Playtex, Inc.,<sup>171</sup> an FDA-mandated warning stated that “[t]ampons are *associated* with Toxic Shock Syndrome.” (emphasis added).<sup>172</sup> In upholding a verdict for the plaintiff, the court might be saying that the warning should have said that tampons *cause* toxic shock syndrome.<sup>173</sup> Overwarning of this sort could deter consumers from using needed products.<sup>174</sup> For instance, jury verdicts against vaccine manufactures discourage the use of vaccines.<sup>175</sup> The utility of information on the package to doctors would also decrease, as doctors might then disregard additional information if they suspect it is unsubstantiated by scientific fact.<sup>176</sup> Uniform labels,

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<sup>166</sup>See Geiger, *supra* note 33, at 411; *see also* H.R. Rep. No. 853, 94<sup>th</sup> Cong., 2d Sess. 45-46 (1976) (“The Committee recognizes that if a substantial number of different requirements applicable to medical devices are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”)

<sup>167</sup>See Del Giorno, *supra* note 42, at 651.

<sup>168</sup>See Del Giorno, *supra* note 42, at 652. In contrast, the FDA provides guidelines which mandate that only scientifically credible information be included in drug labeling. 21 C.F.R. § 1.21(c).

<sup>169</sup>Schafrick, *supra* note 44.

<sup>170</sup>See Schafrick, *supra* note 44. As Schafrick writes, “Decisions that allow juries to dispute government-approved assessments regarding a hazard have the effect of encouraging manufacturers to overstate the potential hazards from their products.” *Id.*

<sup>171</sup>O’Gilvie v. International Playtex Inc., 821 F.2d 1438 (10<sup>th</sup> Cir. 1987).

<sup>172</sup>821 F.2d at 1442, n. 2. The FDA warning is codified at 21 C.F.R. §801.430 (1995).

<sup>173</sup>See Schafrick, *supra* note 44.

<sup>174</sup>See Schafrick, *supra* note 44.

<sup>175</sup>See Clarke, *supra* note 98, at 533.

<sup>176</sup>See Del Giorno, *supra* note 42, at 652. The Supreme Court stated in Finn v. G.D. Searle & Co., 35 Cal. 3d 691, 677 P.2d 1147 (1984):

[I]t seems obvious that liability ought not to be imposed for failure-to-warn based on every piece of information

on the other hand, by the nation's premier expert in safety – the FDA – provide a much more effective way to warn consumers of the real risks associated with a product. Indeed, “More effective labeling will occur [not as a result of the tort system, but] only when there is a uniform vocabulary, so that the labels use the same language to warn of comparable hazards from different products.”<sup>177</sup> The FDA system of balancing risks and costs is simply a more effective way of ensuring that consumers are adequately aware of the risks associated with a product.<sup>178</sup>

National uniformity would also safeguard the needed agenda-setting role of states. State regulations more protective than federal regulations have the desirable effect of forcing the FDA to take action by moving the item up on the FDA's agenda.<sup>179</sup> For example, in 1989, California's Scientific Advisory Panel's subpanel on Reproductive Toxicity recommended that aspirin be listed as causing reproductive toxicity if used during the third trimester of pregnancy.<sup>180</sup> Complying with the California rule, however, would have conflicted with a proposed FDA rule for an internal analgesics monograph.<sup>181</sup> As a response to the California requirement, the Nonprescription Drug Manufacturer's Association petitioned the FDA to implement a third-trimester aspirin warning prior to publication of the final monograph, which the FDA did.<sup>182</sup> FDAMA embraces this state's agenda-setting role, and has included provisions whereby states can petition the FDA to impose additional safety requirements for OTC drugs.<sup>183</sup> Indeed, the FDA “has not failed in any case in the OTC area where action was otherwise warranted, on the basis of resources.”<sup>184</sup> This system ensures that states play a role

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...available... Moreover, both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed on a manufacturer an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given.

*Id.* at 697, 677 P.2d at 1153, cited at Del Giorno, *supra* note 42, at 656, n. 147.

<sup>177</sup>Schaflick, *supra* note 44.

<sup>178</sup>*See* Green, *supra* note 149, at 477 (“[I]t seems plain that the FDA, with its expertise, can reach more accurate decisions than can a common law jury.”)

<sup>179</sup>*See* Gelbert, *supra* note 80, at 658-659.

<sup>180</sup>*See id.* at 659.

<sup>181</sup>*See id.*

<sup>182</sup>*See id.*

<sup>183</sup>21 U.S.C. § 379(r); FDAMA § 412(a); FDCA § 751; 21 U.S.C. 379(s); FDAMA § 412(d); FDCA § 752(b).

<sup>184</sup>143 CONG. REC. S9846 (Sept. 24, 1997) (statement of Sen. Jeffords).

in setting the administrative agenda, yet at the same time, manufacturers would not be forced to adhere to different liability rules and be subject to tort liability where they have complied with the scientifically tested safety requirements of the FDA.

This analysis indicates that in balancing safety versus innovation, the FDA and Congress should take measures to satisfy the need for speedy access to needed drugs. One of the top congressional “findings” in writing FDAMA was that “prompt approval of safe and effective new drugs. . . is critical to the improvement of public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and death.”<sup>185</sup> The drug supply is already as safe as it could be. State regulation is simply unnecessary and carries with it the undesirable side effects of increasing costs and deterring usage. Innovation is a goal that the FDA should try to achieve. Indeed, Congress explicitly called on the FDA to “promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability.”<sup>186</sup>

### *E. The Trade-Off Between National Uniformity and State Product Liability Suits*

In order to tilt the FDA’s objective towards ensuring that innovative products are developed in a cost-effective and timely matter, Congress needs to do more than merely establish nationally uniform standards.

Given the benefits of national uniformity, there appears to be no reason why Congress and the FDA should

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<sup>185</sup>FDAMA § 101. Other findings by Congress included, “2) that public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; 3) that provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be – A) reauthorized for an additional five years, with certain technical improvements; and B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; 4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services. . .” *Id.*

<sup>186</sup>FDAMA § 101; *see also* S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 345.

allow states through their tort law to intrude or compromise the benefits of national uniformity and to preclude innovation. FDA regulations simply are not mere minimum standards.<sup>187</sup> State tort law generally is necessary to encourage potential tortfeasors to take individual circumstances into account.<sup>188</sup> But the pharmaceutical industry is fundamentally different from other industries in which tort law is needed.<sup>189</sup> The FDA drug approval process contemplates individualized drug approval to each drug and includes an individualized assessment of risks and benefits.<sup>190</sup> Because manufacturers cannot build in additional safety measures through design changes, the best the FDA can do to safeguard safety is to ensure that the drug's efficacy sufficiently outweighs the risk of adverse reactions.<sup>191</sup> Tort law simply provides no additional benefit to safety.

Opponents of preemption argue that since many injuries occur after the placement of the drug in the market,<sup>192</sup> allowing state tort claims to be preempted would preclude injured people from being compensated. Tort law, however, is not the answer. Manufacturers already have an incentive to report adverse effects that occur post-approval, since the FDA requires manufacturers to revise labeling and warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug."<sup>193</sup> "These results can then be examined in light of premarketing data, which both the FDA and drug manufacturers are required to maintain."<sup>194</sup> Federal regulations also compel manufacturers to report "any new side effect, adverse reaction,

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<sup>187</sup>See Rissier, *supra* note 13, at 1423.

<sup>188</sup>See *id.*

<sup>189</sup>See *id.*

<sup>190</sup>See *id.*

<sup>191</sup>See Green, *supra* note 149, at 474. "Unlike durable goods, pharmaceuticals cannot be designed differently, in the sense of modifying (or adding) to the product so as to build in more safety." *Id.*

<sup>192</sup>See Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L. J. 194, 228 (1987) ("A review of . . . cases shows that the great majority of suits are predicated on actions or omissions that took place after the drug or device entered the market.")

<sup>193</sup>21 C.F.R. § 201.57(e); *see also* 21 C.F.R. §314.80(a). Manufacturers must also submit reports describing its action in response to adverse reports, any post-approval studies performed on a drug, published reports or studies, or foreign reports of the drug. 21 C.F.R. §§ 314.80(b)-(c).

<sup>194</sup>Rissier, *supra* note 13, at 1415.

or toxicity,” whether or not drug related.<sup>195</sup> Failure to report results in severe penalties.<sup>196</sup> By removing tort liability, manufacturers may even be more likely to report adverse effects to the FDA. Since adverse reports to the FDA are discoverable for products liability plaintiffs, manufacturers are reluctant to report adverse side effects, however unscientifically proven or however rare they may be, to the FDA for fear that plaintiffs will use such reports against them in tort actions.<sup>197</sup> Preempting state tort suits is especially important in OTC-switch cases, since plaintiffs have an easier method of obtaining proof of failure-to-warn. Because OTC-switch drugs do not contain as comprehensive of information as what is located in the Physician’s Desk Reference (“PDR”), if state tort suits were not preempted, plaintiffs could simply cite the PDR as evidence that the OTC-switch drug had a known and foreseeable risk that the OTC-switch drug manufacturer failed to include in its labeling.<sup>198</sup>

Tort law also works against national uniformity’s goal of reducing drug costs and availability. While national uniformity would reduce the cost of complying with different labeling requirements, state product liability suits have “done little to further product safety” but have instead been an “active catalyst” for raising the costs of drugs.<sup>199</sup> As the California Supreme Court said in Brown v. Superior Court<sup>200</sup> in noting that strict liability is meant to deter manufacturers from manufacturing unsafe products:

Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs — added to the delay required to obtain approval for the release of the product from the FDA would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risk, perhaps serious ones, might accompany their introduction.”<sup>201</sup>

Preemption encourages drug manufacturers to develop safer drugs in a more timely matter. The “economic

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<sup>195</sup>The FDA requires label modification “as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.” 21 C.F.R. § 201.57(e).

<sup>196</sup>See Rissier, *supra* note 13, at 1415.

<sup>197</sup>See *id.* at 1406.

<sup>198</sup>See *id.* at 1399.

<sup>199</sup>Walsh, *supra* note 111, at 1021.

<sup>200</sup>*Brown v. Superior Court*, 751 P.2d 470 (Cal. App. Dep’t Super. Ct. 1988).



unpredictability” of tort actions chills the manufacturers’ drive to develop new products or market old ones.<sup>202</sup> Manufacturers will be deterred from research and development, and manufacturers who do develop new drugs will “test them longer and more carefully, thereby delaying the availability of the drug and its therapeutic advantages to society.”<sup>203</sup> Tort suits and the tendency of manufacturers to place unsubstantiated warnings on products to avoid tort liability can also have the indirect effect of withdrawing a needed product from the market. For example, the prescription drug Bendectin was prescribed to millions of pregnant women between 1956 and 1983 to relieve problems associated with morning sickness. In 1983, the drug was withdrawn from the market as a result of claims that it caused birth defects.<sup>204</sup> By 1995, Bendectin had spent nearly \$100 million defending itself,<sup>205</sup> despite the fact that an FDA advisory committee had concluded that there was no evidence of a link between the drug and an increased risk of birth defects.<sup>206</sup> The FDA continues to approve Bendectin and its principal ingredient is still in use in many OTC medicines. Tort liability has also caused manufacturers to restrict the sale and distribution of vaccines.<sup>207</sup> For instance, two of the three manufacturers of the DPT vaccine withdrew from the market, citing risks of legal liability, legal costs incurred in defending suits, and the rising costs of insurance, as the primary reasons for their withdrawal.<sup>208</sup>

From this analysis, we can conclude that moving toward national uniformity for drugs would have a great deal of benefit. Less burdensome regulations enable the FDA to work toward its goal of encouraging drug innovation and in ensuring access to needed pharmaceuticals by easing burdens associated with multiple regulation. What we can also have seen from this analysis is that removing barriers imposed by state

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<sup>202</sup> See Rissier, *supra* note 13, at 1406.

<sup>203</sup> Green, *supra* note 149, at 467; *see also* Punitive Damages: Tort Reform and FDA Defenses: Hearings on S.671 and S.672 Before the Senate Comm. on the Judiciary, 104<sup>th</sup> Cong. 141-142 (1995) (statement of Sen. Nancy Landon Kassebaum)

<sup>204</sup> See Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE, THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* (Peter W. Huber & Robert E. Litan, eds. 1991), at 334, 337-341.

<sup>205</sup> See Punitive Damages: Tort Reform and FDA Defenses: Hearings on S. 671 and S.672 Before the Senate Comm. on the Judiciary, 104<sup>th</sup> Cong. 141-1423 (1995) (statement of Sen. Nancy Landon Kassebaum).

<sup>206</sup> See 45 Fed. Reg. 80, 741, 80, 742 (1980).

<sup>207</sup> See Clarke, *supra* note 98, at 516.

<sup>208</sup> See *id.* at 544, n.. 17

*legislatures* is not enough. Burdens on the pharmaceutical industry – in terms of reducing innovation, increasing costs, and reducing supply – still exist if state *courts* are allowed to impose additional regulatory measures on pharmaceutical companies. True national uniformity – and any effective goal of realizing international standards and encouraging innovation – can only be achieved if all burdens imposed by the states are removed.

## V. Medical Devices

### A. *History of Medical Device Regulation*

The 1938 Act gave the FDA limited power over medical devices. The Act prohibited the entry of misbranded or adulterated medical devices into interstate commerce,<sup>209</sup> and imposed requirements for the labeling of medical devices.<sup>210</sup> The Act did not, however, require premarket safety testing for medical devices nor did it require good manufacturing practices.<sup>211</sup> In 1970, the Cooper Committee, formed by the Secretary of Health, Education and Welfare, conducted a study which reported that medical devices had caused or contributed to over 700 deaths and over 10,000 injuries during a ten-year period.<sup>212</sup> Concern over the safety of medical devices prompted Congress to grant enhanced power to the FDA to regulate. The 1976 Medical Device Amendments (“MDA”) and its subsequent regulations subjected new medical devices to the kind of premarket approval processes required for drugs.<sup>213</sup> Increased control over labeling and the imposition of good manufacturing practices, combined with increased enforcement authority, helped to put make the amendments even stronger.<sup>214</sup> Congress also created a three-tier system for medical device regulation, based

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<sup>209</sup>Pub. L. No. 75-717. § 501, 52 Stat. at 1049-1050; 21 C.F.R. § 502.

<sup>210</sup>See Howard M. Holstein & Edward C. Wilson, *Developments in Medical Device Regulation*, in FUNDAMENTALS OF LAW AND REGULATION 258 (Edward P. Brady et al. eds, 1997)

<sup>211</sup>See Robert R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last 50 Years*, 50 FOOD & DRUG L. J. 163, 163-164 (1995).

<sup>212</sup>See *id.* at 165.

<sup>213</sup>21 U.S.C. § 351(f)(1). “A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.” 21 C.F.R. § 814.80. See Larry R. Pilot & Daniel R. Waldmann, *Food and Drug Administration Modernization Act of 1997: Medical Device Provisions*, 53 FOOD & DRUG L. J. 267, 269 (1998).

<sup>214</sup>General controls, relating primarily to reporting, recordkeeping, and adequate labeling and good manufacturing practices,

on increasing levels of risk to users.<sup>215</sup>

The history of medical devices and preemption provides the clearest example of how Congress signaled out a specific FDA-regulated product for special treatment. Long before the possibility of preemption was ever seriously discussed for OTC drugs or cosmetics, the MDA contained an express preemption provision.<sup>216</sup> The preemption provision of the MDA was a response to state laws enacted in the wake of quality problems with unregulated medical devices, such as the Dalkon Shield and cardiac pacemakers.<sup>217</sup> In the 1970s, at least 13 states had enacted laws to regulate the safety of medical devices.<sup>218</sup> California's Sherman Law was the most comprehensive.<sup>219</sup> The Sherman Food, Drug, and Cosmetic law, adopted in 1970, required premarket approval of new medical devices, manufacturer compliance with good manufacturing practices, and inspection

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provide the minimum level of protection for medical devices. The general controls are set forth in 21 U.S.C. §§ 351, 352, 360, 360f, 360h, 360i, and 360j; 21 C.F.R. § 800 et. seq.

<sup>215</sup>Pub. L. No. 75-717 at § 502, 52 Stat. at 1050-1051. For Class I devices (such as bandages), general controls are considered adequate for the reasonable effectiveness and safety of the device. 21 U.S.C. § 360c(a)(1)(A). Class II devices (such as tampons) consists of devices for which general controls are not sufficient to ensure safety and effectiveness, but there is information to develop performance standards. 21 U.S.C. § 360c(a)(1)(B). Class II devices are subject to "special controls," which may include specific performance standards, postmarket surveillance, patient registries, recommendations or guidelines. 21 U.S.C. § 360d(2); 21 C.F.R. §§ 861.7, 860.3(c)(2); 880.2920, 880.5570. Class III devices (such as artificial heart valves) are defined as those that support or sustain human life, are of substantial importance in preventing the impairment of human health, and present a potential, unreasonable risk of injury. 21 C.F.R. § 860.3(c)(3). Before marketing, Class III devices must be "substantially equivalent" to devices in existence before May 28, 1978, or grant premarket approval after scientific review. 21 U.S.C. § 360e; 21 C.F.R. §§ 814.20, 814.80. Class III devices must also satisfy post-approval regulation, such as by maintaining records and reporting to the FDA. 21 U.S.C. § 360i.

<sup>216</sup>*See supra*

<sup>217</sup>*See* Leflar, *supra* note 54, at 703. For instance, at the time of enactment of the MDA, the Dalkon Shield, a contraceptive device, had been linked to sixteen deaths and twenty-five miscarriages, with over 500 lawsuits pending against the manufacturer of the Shield. H.R. Rep. 853, 94<sup>th</sup> Cong., 2d Sess. (1976). Problems with cardiac pacemakers had necessitated 34 voluntary recalls of 23,000 units. *See id.*

<sup>218</sup>*See* Leflar, *supra* note 54, at 748, n. 66; 1970 ARIZ. SESS. LAWS 94, ARIZ. REV. STAT. ANN. §36-1901 (West 1970); 1970 CAL. STAT. 1573, CAL. HEALTH & SAFETY CODE §§ 26000-26851 (West 1970); 1970 CAL. STAT. 1514, CAL. BUS. & PROF. CODE §3365 (West 1970); 1972 CONN. ACTS 295, CONN. GEN. STAT. ANN. §§ 20-403, -404 (West 1972); 1976 KY. ACTS 276, KY. REV. STAT. ANN. § 334.200 (Michie 1976); 1975 ME. ACTS 463, ME. REV. STAT. ANN. Tit. 32, §§ 1658-C to 1658-E (West 1975); 1973 MINN. LAWS 383, MINN. STAT. ANN. § 145-43 (West 1973); 1973 N.J. LAWS. 19, N.J. STAT. ANN. §§ 49.9A-23 to -25 (West 1973); 1975 N.Y. LAWS 799, N.Y. GEN. BUS. LAW § 784 (McKinney 1975); 1969 OHIO LAWS 133, OHIO REV. CODE ANN. § 4747.09 (Anderson 1969); 1975 OR. LAWS 673, 675, OR. REV. STAT. §§ 694.036, 694.136 (1975); 1969 TEX. GEN. LAWS 366, TEX. REV. CIV. STAT. ANN. art. 4566-1.14 (West 1969); 1973 W. VA. ACTS 59, W. VA. CODE § 30-26-14 (1973); 1973 WASH. LAWS 106, WASH. REV. CODE § 18.35.110(2)(e) (1973). *See also* 21 C.F.R. §§ 808.53-808.101 (1996).

<sup>219</sup>1970 CAL. STAT. § 1573, CAL. HEALTH & SAFETY CODE §§ 2600-26851 (West 1970). *See* Susan Foote, Loops and Loopholes: Hazardous Device Regulation under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act, 7 ECOLOGY L. Q. 101, 128-30 (1978).

of establishments with medical devices.<sup>220</sup> Congress felt that such laws would disrupt interstate commerce, so they enacted the MDA to explicitly preempt such laws.<sup>221</sup> At the same time, however, Congress felt that states with stricter requirements than that mandated by federal law should be able to enforce them with FDA permission.<sup>222</sup> Consequently, section b of the preemption provision explicitly allowed states to ask the FDA for continued application of a stricter requirement.<sup>223</sup>

Since Medtronic, there has been a great deal of confusion as to exactly what kinds of claims the MDA may preempt. The Medtronic decision seems to eliminate preemption as a defense for devices cleared under the § 510(k) process; whether preemption exists for investigational devices and devices approved by the FDA through the more regulatory-intensive premarket approval process (“PMA”) is still subject to debate.<sup>224</sup>

Since Medtronic, at least some courts have preempted state product liability suits where the device had

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<sup>220</sup>See 1970 CAL. STAT. § 1573, CAL. HEALTH & SAFETY CODE §§ 2600-26851 (West 1970); H.R. Rep. 94-853, 94<sup>th</sup> Cong., 2d Sess. (1976). For instance, as a result of the Sherman Law, intrauterine devices had to withstand premarket clearance in California. See *id.*

<sup>221</sup>H.R. Rep. No. 853, 94<sup>th</sup> Cong., 2d Sess. 45-46 (1976) (“The Congress recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”)

<sup>222</sup>See Leflar, *supra* note 54, at 703.

<sup>223</sup>Section 360k(b) states:

Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

- 1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
- 2) the requirement –
  - a. if required by compelling local circumstances, and
  - b. compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

*Id.* at 21 U.S.C. § 360k(b).

<sup>224</sup>See Mary Beth Nerass, *Medical Device Preemption After Medtronic, Inc., v. Lohr*, 51 FOOD & DRUG L. J. 619, 629 (1996).

undergone either premarket testing<sup>225</sup> or had been subject to an investigational device exemption (“IDE”).<sup>226</sup> The FDA, in response to this trend, had tried but failed, to issue a rule that the MDA does not preempt state liability actions.<sup>227</sup> This rule would have specifically stated that clearance or approval under the § 510(k) substantial equivalence process, the § 515 premarket approval process and the § 520(g) IDE would not have been entitled to preemptive effect.<sup>228</sup> The failure to enact the rule added to the explicit rejection of the proposed rule by some courts<sup>229</sup> has left the issue unclear.

### B. *The Need for National Uniformity for Medical Devices*

In the twenty-five years between the enactment of the MDA and FDAMA, Congress failed to include a similar preemption provision for drugs, cosmetics, or food. Is there any reason why Congress might not have sought

<sup>225</sup>See Noah, *supra* note 53, at 211 (“Device manufacturers . . . have benefitted from the gradual extension of the federal preemption doctrine from fairly straightforward cases involving substantive agency requirements expressed in the form of regulations to more difficult cases involving FDA requirements expressed during a rigorous, but individualized preapproval process.”); see also Peter L. Puciloski, *Courts and FDA Wrestle with Preemption Issues*, NAT. L. J. (August 31, 1998) at B11. Some courts have allowed devices which have undergone premarket approval to preempt state product liability actions. See, e.g., Fry v. Allergan Medical Optics, 695 A.2d 511, 516 (R.I. 1997) (court found a “specific federal interest” in premarket approval of an intraocular lens); Mitchell v. Collagen, 126 F.3d 902, 911 (7<sup>th</sup> Cir. 1997) (“[T]he premarket approval process constitutes a specific federal interest as contemplated in Medtronic and that, therefore, the FDA approval served to impose strict FDA requirements on the defendant.”) In contrast, some courts have allowed tort suits to proceed, because they construe such suits as “general obligations,” applicable even if a device has undergone premarket approval. See, e.g., Wutzke v. Schwaegler, 940 P.2d 1386 (Wash. Ct. App. 1997) (state tort is a matter of “general applicability,” so preemption is not given effect); Sowell v. Bausch & Lomb, 656 N.Y.S.2d 16 (N.Y. App. Div. 1997) (premarket approval is not a specific federal requirement); Walker v. Johnson & Johnson Vision Products, 552 N.W.2d 679 (Mich. Ct. App. 1996) (premarket approval is not a specific federal regulation and tort actions are not specific state regulations). For more information, see Daniel G. Jarcho, *Premarket Approval and Federal Preemption of Product Liability Claims in the Wake of Medtronic, Inc. v. Lohr*, 51 FOOD & DRUG L. J. 613 (1996).

<sup>226</sup>See, e.g., Martin v. Teletronic Pacing Systems, 105 F.3d 1090 (6<sup>th</sup> Cir. 1997) (preemption applied to claims for cardiac pacemaker granted under § 520(g)).

<sup>227</sup>Withdrawal of Proposed Rule, 63 Fed. Reg. 39789 (July 24, 1998); 62 Fed. Reg. 65384 (1997). The FDA sought to “clarify and codify the agency’s longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act.” *Id.* The agency based its rejection of the rule on its failure to “share its thinking” on preemption with Congress during debates of FDAMA. The FDA also noted that it had shared an early draft of the regulation with the Public Citizen Litigation group, the attorneys for the plaintiff in Lohr, but it had not published a notice in the Federal Register. See Puciloski, *supra* note 225, at B11.

<sup>228</sup>Exemption from Federal Preemption of State and Local Medical Device Requirements, 62 Fed. Reg. 65385 (1997), codified at 21 C.F.R. § 808.1(d)(12) (proposed Dec. 8, 1997).

<sup>229</sup>Some courts have explicitly rejected the proposed FDA rule. See, e.g., Easterling v. Cardiac Pacemakers, 986 F. Supp. 366 (E.D. La. 1998) (FDA proposed rule was “neither controlling nor persuasive); Worthy v. Collagen, 967 S.W.2d 360 (Texas 1998) (rejecting proposed FDA rule and found premarket approval process to be “sufficiently specific to have preemptive effect.).

to enact similar protections for drugs as for medical devices? What spurred Congress to write up a specific statute to preempt medical devices? Professor Arthur Miller, in his oral argument in the Medtronic case posited that perhaps “the sociology of the device industry and the critical character of the device industry as perceived in the seventies, the need for innovation, the need for availability, motivated Congress” to only preempt medical devices.<sup>230</sup> These rationales appear to be equally applicable, however, to drugs. Courts’ subsequent interpretation of the MDA’s preemption provision caused an unwarranted departure from the way courts interpreted implicit preemption for drugs.<sup>231</sup> Courts, in essence, were more willing to find preemption for medical devices than for drugs,<sup>232</sup> despite the fact that in the 1970s and 1980s, the safety record for medical devices was inferior to that for drugs. In contrast to drugs, FDA regulation of medical devices was significantly more lax, so lax so as to prompt congressional hearings on the subject.<sup>233</sup> For example, during the eight years after enactment of the MDA, the FDA failed to have a mandatory reporting system for device-related injuries and product failures, an oversight cited by the General Accounting Office to be inadequate.<sup>234</sup> FDA approval of the § 501(k) substantial equivalence process may be more of a “rubber stamp” than a thorough review.<sup>235</sup> As Wilson notes, as of 1993, the FDA had an “unofficial policy that 98% of all § 510(k) substantial equivalence applications be approved.”<sup>236</sup> Another example is performance

<sup>230</sup>Transcript, at \*26. These sentiments were echoed by Carrier where he asks the following questions: “Does the inclusion of the provision mean that Congress did not consider medical devices as potentially dangerous as drugs, which also might be inferred from pre-Lohr court decisions construing the provision? Did Congress perceive that the nature of medical device research and development was sufficiently different from that of drugs that additional encouragement in the form of tort preemption was required? Was the preemption provision a result of legislative log-rolling, in which passage of the Act was ensured by the inclusion of a vague preemption provision that the courts would worry about later? Or, as seems most plausible, did Congress expect states to continue to attempt to concurrently regulate medical devices through positive enactment in a way in which they had not attempted to regulate drugs for many years?” Carrier, *supra* note **what**, at 599.

<sup>231</sup>See Porter, *supra* note 71, at 11.

<sup>232</sup>See *supra*.

<sup>233</sup>See, e.g., Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, 98<sup>th</sup> Cong., 1<sup>st</sup> Sess., Medical Device Regulation: The FDA’s Neglected Child 1, 4 (Comm. Print. 1983), as cited in Ashley W. Warren, *Preemption of Claims Related to Class III Medical Devices: Are the Federal Objectives of Public Health and Safety Furthered or Hindered*, 49 SO. METH. U. L.R. 619, 644 (1996); see also “Less Than the Sum of Its Parts,” H.R. Rep. No. 103-N, 103d Cong., 1<sup>st</sup> Sess. 5 (1993) (report highly critical of agency’s treatment of medical devices); see also Pilot, *supra* note 213, at 270.

<sup>234</sup>See Leflar, *supra* note 54, at 748, n. 115; see also U.S. GEN. ACCOUNTING OFFICE, MEDICAL DEVICES: EARLY WARNINGS OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING (1986).

<sup>235</sup>See Wilson, *supra* note 59, at 425.

<sup>236</sup>Report by the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, Less than the Sum of its Parts: Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration

standards for Class II medical devices. Under the MDA, the FDA was supposed to promulgate performance standards for Class II medical devices.<sup>237</sup> Analysts have estimated, however, that due to limited resources and the complexity of procedures for creating such standards, it would take nearly 50,000 staff years for the FDA to finish writing up the standards.<sup>238</sup> As a result of the FDA's inability to fulfill the MDA's mandate on performance standards, the Act has been amended to allow Class II devices to be regulated through less rigorous special controls.<sup>239</sup>

The arguments in favor of national uniformity for drugs – such as increasing access to needed supplies, encouraging innovation, and decreasing costs – are also applicable to the medical device context. Indeed, where the FDA has monitored the safety of medical devices, there is no reason to treat them any different than drugs. Congress should apply preemption in instances where the FDA has thoroughly tested devices or for which there is a necessary element of experimentation. The “regulation-intensive” and device-specific PMA and IDE processes are “safety-oriented” and can further a purpose of the MDA to encourage research and development.<sup>240</sup> The PMA process has been characterized as “extensive” and “rigorous,” where the FDA extensively reviews design, labeling and manufacturing data specific to each product to ensure that there is a “reasonable assurance” that the product is safe and effective.<sup>241</sup> Likewise, while investigational devices are exempt from most safety, efficacy and performance standards,<sup>242</sup> device-specific regulations apply.<sup>243</sup> Further, while FDA regulations “do not specify the safe and effective design,” they do specify “the

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Center for Devices and Radiological Health, 103<sup>rd</sup> Cong., 1<sup>st</sup> Sess, 24 (1993); see also Report of the Subcommittee on Oversight and Investigations, Medical Device Regulation: The FDA's Neglected Child 1, 4 (Comm. Print. 1983); Wilson, *supra* note 59, at 425, 427, n. 150

<sup>237</sup> See Walsh, *supra* note 111, at 946-947.

<sup>238</sup> See *id.*

<sup>239</sup> See *id.*; For examples, see Warren, *supra* note 233, at 645-647.

<sup>240</sup> Scott W. Sayler & Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After Medtronic, Inc., v. Lohr*, 6 ANNALS HEALTH L. 185, 200. (“[U]nlike in the section 510(k) context, state common law claims concerning PMA and IDE devices are capable of interfering with or impeding implementation of specific federal interests.”) Indeed, one of the purposes of the MDA was to encourage research and development for medical devices. S. Rep. No. 94-33, at 1-2 (1976).

<sup>241</sup> See Sayler, *supra* note 240, at 201-202.

<sup>242</sup> 21 C.F.R. §812.1(a).

<sup>243</sup> See Sayler, *supra* note 240, at 202.

procedures for determining whether the experimental design is safe and effective.”<sup>244</sup>

National uniformity and the need to encourage innovation is such a worthy goal that disparities in levels of safety should be resolved not by varying preemption according to differing levels of safety standards, but by increasing FDA monitoring of the safety of medical devices. The two tensions operating for drug regulation – the necessity of ensuring the safety of the product balanced against the desirability of inducing innovative products to speedily come to market – operates equally for medical devices. Through the enactment of the 1990 Safe Medical Device Amendments,<sup>245</sup> the 1992 Medical Device Amendments,<sup>246</sup> and FDAMA, Congress has taken measures to increase the safety of medical devices. In the 1990 Safe Medical Device Act, Congress required device manufacturers filing § 510(k) premarket notifications to make available information relating to safety and efficacy and also set a statutory standard for FDA “substantial equivalence” determinations.<sup>247</sup> FDAMA made further revisions as it provided the opportunity for the FDA to condition approval on postmarket controls, and required that foreign establishments register with the FDA.<sup>248</sup>

Also, since there is a definitional overlap between medical devices and drugs,<sup>249</sup> differences in standards increase the chances of FDA misclassification. Regulation of drugs is considerably more expensive, takes longer, and is more extensive than testing for medical devices.<sup>250</sup> Lessened regulatory burdens combined

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<sup>244</sup>Sayler, *supra* note 240, at 191, 202, citing Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7<sup>th</sup> Cir. 1992).

<sup>245</sup>Pub. L. No. 101-629, 104 Stat. 4511 (1990)

<sup>246</sup>Pub. L. No. 102-300, 106 Stat. 238 (1992).

<sup>247</sup>21 U.S.C. §360c(i)(1)(3) (1994). The Safe Medical Device Amendments also require manufacturers to report deaths to the FDA. 21 U.S.C. § 360i(b). For more information on the Safe Medical Device Amendments and the 1992 Medical Device Amendments, see Munsey, *supra* note 211, at 170-176.

<sup>248</sup>See Pilot, *supra* note 213, at 277.

<sup>249</sup>The definitions of drugs and devices both include 1) products recognized in the National Formulary or U.S. Pharmacopeia; 2) products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, and 3) products that are intended to affect the structure or any function of the body or man or other animals. Gail H. Javitt, *I’ve Got You Under My Skin – and I Can’t Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 FOOD & DRUG L. J. 553, 573, n. 30 (1994).

<sup>250</sup>See *id.* at 568.



with preemption of state tort suits encourages manufacturers to attempt to convince the FDA to classify borderline products as devices.<sup>251</sup> For example, manufacturers of Cu-7 IUD tried in the late 1980s to argue that the product was really a device rather than a drug.<sup>252</sup> The FDA has previously classified an IED that containing heavy metals or biologically active substances as a drug,<sup>253</sup> but the defendants argued that “transitional language in the MDA merited reclassifying the Cu-7 as a device.”<sup>254</sup> Although the FDA ultimately rejected the manufacturer’s attempt, leveling out the burdens imposed on manufacturers of drugs and medical devices would reduce the incentive for manufacturers to attempt reclassification, either as a medical device rather than a drug, or as a Class I device rather than the more heavily-regulated Class III device. Consumer safety would be the benefactor of increased regulation.

Thus, since there have been significant strides in increasing the safety of medical devices, the same forces operating to encourage preemption of both positive legislative enactments and state tort suits for drugs should work to ensure that the balance shifts towards encouraging the development of innovative medical devices. Indeed, the legislative history of the MDA suggests that one of its purposes was to encourage innovation.<sup>255</sup> Congress should take steps now to fulfill this mandate. FDAMA is a step in the right direction. FDAMA encourages the spirit of safeguarding speedy access to medical devices by making significant changes in expediting reclassification of medical devices, and in simplifying the recognition and application of national/international standards.<sup>256</sup> But FDAMA does not go far enough. As with drugs, Congress should explicitly preempt state product liability suits for medical devices. The secondary effects of state tort suits

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<sup>251</sup> See *id.* “[P]ermitt[ing] preemption for devices, while drugs are subject to liability, increases manufacturers’ incentives to seek device classification, and, for the consumer injured by a medical device, raises the stakes of any misclassification by the FDA.” *Id.* at 569.

<sup>252</sup> See *id.* at 568.

<sup>253</sup> See *id.*; see *Callan v. G.D. Searle & Co.*, 709 F.Supp. 662 (D. Md. 1989); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D. N.J. 1988); *Tarollo v. G.D. Searle & Co.*, 704 F.Supp. 653 (D. S.C. 1988); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988). In *Tarollo*, the court denied summary judgment, and did not rule out the possibility that Cu-7 was classified as a device rather than a drug. See 704 F.Supp. at 656.

<sup>254</sup> Javitt, *supra* note 249, at 568.

<sup>255</sup> S. Rep. No. 94-33, at 1-2 (1976), quoted in Carrier, *supra* note 29, at 548.

<sup>256</sup> See Pilot, *supra* note 213, at 277.

– a form of indirect state regulation – result in higher cost and lessened innovation. Just as the MDA sought to solve the same problems by preempting state positive legislative enactments, Congress should undertake a similar position by preempting state tort suits, thereby eliminating an unnecessary source of regulation.

## VI. COSMETICS

### A.

#### History of Cosmetics Regulation

The FDA began regulating cosmetics in 1938. An 1897 version of the 1906 Pure Food and Drug Act provided for federal regulation of cosmetics, but the provision was dropped for political reasons.<sup>257</sup> After Franklin Roosevelt assumed the presidency in 1933, Senator Royal S. Copeland of New York introduced legislation to strengthen the FDA's powers under the 1906 Pure Food and Drug Act.<sup>258</sup> Prior to the enactment of the 1938 Act, states regulated cosmetics.<sup>259</sup> Congress, concerned with the lack of uniformity in the regulation of cosmetics and provoked during the Senate debates by a report of a woman injured by eyelash dye,<sup>260</sup> passed

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<sup>257</sup> See Thomas F. Anderson, Note, *Food, Drug or Both? Dual Classification Under the Federal Food, Drug, and Cosmetic Act*, 1984 ILL. L. REV. 987, 989 (1984), citing Anderson, *Pioneer Statutes: The Pure Food and Drugs Act of 1906*, 13 J. PUB. L. 189 (1964).

<sup>258</sup> Pub. L. No. 59-384, 34 Stat. 768 (1906); See Thomas J. Donegan, *Fifty Years of Cosmetic Safety: A Government and Industry Partnership*, 50 FOOD & DRUG L. J. 151, 152 (1995).

<sup>259</sup> See *id.*

<sup>260</sup> See Jacqueline A. Greff, *Regulation of Cosmetics That are Also Drugs*, 51 FOOD & DRUG L.J. 242, 244 (1996); Donegan *supra* note 258, at 152; 78 CONG. REC. 8958; S. Rep. No. 493, 73d Cong, 2d Sess. (1934), reprinted in 2 A LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 720, 829 (1970).

the 1938 Act to prohibit the sale of adulterated<sup>261</sup> or misbranded cosmetics.<sup>262</sup> Under the Act, cosmetics are also unlawful if the label or container is false or misleading,<sup>263</sup> or if it fails to bear required information.<sup>264</sup> In 1960, Congress passed the Color Additive Amendments, which prohibited the use of a color additive unless there was a regulation listing such additive for use.<sup>265</sup> The Color Additive Amendments also contained a hotly-debated provision – the Delaney Clause.<sup>266</sup> The Delaney Clause sought to protect consumers against cancer-causing ingredients by placing an absolute bar on color additives which “after tests which are appropriate for the evaluation of the safety or additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.”<sup>267</sup> The FDA has also passed regulations to govern the making of cosmetic products. The FDA requires manufacturers to substantiate the safety of each cosmetic product and each ingredient used in the product.<sup>268</sup> In 1974, the FDA derived authority from the Fair Packing and Labeling Act to mandate full ingredient labeling for cosmetic products.<sup>269</sup> FDA regulations also prescribe the method for determining the proper nomenclature for ingredient labeling.<sup>270</sup> The FDA can inspect manufacturing facilities and issue warning letters.<sup>271</sup> Further,

<sup>261</sup>21 U.S.C. § 361; FDCA § 601. A cosmetic is deemed adulterated if a) it bears or contains any poisonous or deleterious substance which may render it injurious to users under conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary and usual; b) it consists in whole or in part of any filthy, putrid, or decomposed substance; c) it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; d) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or e) it is not a hair dye, and it is, or it bears or contains, a color additive which is unsafe within the meaning of § 721(a).

<sup>262</sup>21 U.S.C. § 362; FDCA § 602. A cosmetic is deemed misbranded: a) if its labeling is false or misleading in any particular; b) unless it bears a label containing 1) the name and place of business of the manufacturer, packer, or distributor; and 2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; c) if any word or statement required by the Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual user under customary conditions or purchase and use; d) if its container is so made, formed, or filled as to be misleading; or e) if it is a color additive and its packaging and labeling are not in conformity with regulations issued under section 721.

<sup>263</sup>21 U.S.C. § 362(a)(d); FDCA § 602(a)(d).

<sup>264</sup>21 U.S.C. § 362(b) (c); FDCA § 602(b) (c).

<sup>265</sup>Pub. L. No. 86-618, 74 Stat. 397 (1960).

<sup>266</sup>21 C.F.R. § 740.10.

<sup>267</sup>21 U.S.C. § 379e(b)(5)(B).

<sup>268</sup>21 C.F.R. § 740.10; *see also* S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344.

<sup>269</sup>Pub. L. No. 89-755, §§ 5, 6, 80 Stat. 1296; 15 U.S.C. §§ 1454-55 (1988)); *see also* Donegan, *supra* note 258, at 155.

<sup>270</sup>21 U.S.C. § 701.3 (c).

<sup>271</sup>21 U.S.C. §§ 371-374; FDCA § 701-704.

although the FDA cannot issue product recalls, it can obtain court orders enjoining manufacturers from producing or distributing a product.<sup>272</sup>

Unlike the regulation of drugs, cosmetics are not subject to premarket approval,<sup>273</sup> safety or efficacy testing, good manufacturing practices,<sup>274</sup> or registration.<sup>275</sup> The FDA retains no legal authority to require manufacturers to submit lists of ingredients to the agency, or to report consumer complaints.<sup>276</sup> Congressional proposals to require premarket testing of cosmetics failed.<sup>277</sup> In 1975, the FDA tried to issue regulations defining hypoallergenic to mean a lower potential for causing an allergic reaction, and to require that companies submit information to FDA establishing that in fact their products were hypoallergenic.<sup>278</sup> A federal appeals court rejected the regulations.<sup>279</sup>

Indeed, the FDA has little formal regulatory authority over cosmetics, and instead has relied on a “unique partnership of government oversight and industry self-regulation” to regulate cosmetics.<sup>280</sup> The industry-funded Cosmetic Ingredient Review (“CIR”) became the “cornerstone” of the cosmetic industry’s regulation efforts.<sup>281</sup> Founded in 1976, CIR patterned itself after the FDA’s Over-the-Counter Drug Review to provide independent, public review of frequently-used cosmetic ingredients.<sup>282</sup> An Expert Panel composed of seven scientists and physicians examines scientific data on the safety of cosmetic ingredients.<sup>283</sup> The FDA

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<sup>272</sup>21 U.S.C. §§ 332-334; FDCA § 302-304.

<sup>273</sup>21 U.S.C. § 355(a); FDCA § 505(a).

<sup>274</sup>21 U.S.C. § 355(d)(3); FDCA § 505(d)(3).

<sup>275</sup>21 U.S.C. § 360; FDCA § 510.

<sup>276</sup>143 CONG. REC. S8885 (Sept. 8, 1997) (statement of Sen. Kennedy).

<sup>277</sup>See Greff, *supra* note 260, at 246. In 1977, the FDA said it intended to propose GMP regulations for preservative systems in mascaras as a “first step” toward cosmetic GMPs. 42 Fed. Reg. 54, 837 (Oct. 11, 1977). CTFA sent a petition to the FDA requesting that cosmetics be subject only to cosmetic, not drug, GMPs. See Stephen H. McNamara, *Preparing for Cosmetic GMP – A Legal Perspective*, 35 FOOD DRUG COS. J. 651 (1980). The FDA incorporated CFTA’s GMP letter into the Investigations Operations Manual, but later requested the CFTA to withdraw their petition. See Conversation with John Wenninger, Tech. Dir., CFTA (Feb. 1995), as cited in Greff, *supra* note 260, at 246, 272.

<sup>278</sup>See Stehlin, *Contact Dermatitis: Solutions to Rash Mysteries*, FDA CONSUMER (May 1990).

<sup>279</sup>See *id.*

<sup>280</sup>Donegan, *supra* note 258, at 151.

<sup>281</sup>See *id.* at 156. “The CIR was designed to help each individual company meet its obligation to substantiate the safety of each ingredient and formulation prior to marketing products to the public.” *Id.*

<sup>282</sup>See *id.* The Research Institute for Fragrance Materials performs a similar role for the safety of fragrance ingredients. See *id.*

<sup>283</sup>See *id.* Consumer organizations, scientific and clinical societies and governmental agencies nominate members to the CIR. See *id.* The FDA, the Consumer Federation of America, and the CTFA also appoint three liaison, nonvoting members. See *id.*

also maintains a Voluntary Cosmetic Reporting Program as a means for the cosmetic industry to supply information on the location of manufacturing establishments, the ingredients used to formulate products, and the occurrence of adverse reactions to cosmetic products.<sup>284</sup> FDA regulations establish the procedure for the voluntary registration of cosmetic product establishments, the voluntary filing of cosmetic product ingredients, and the voluntary filing of cosmetic product experiences.<sup>285</sup> The FDA also promulgates regulations for cosmetic labeling.<sup>286</sup> As Thomas J. Donegan, Jr., the Vice-President-Legal & General Counsel of The Cosmetic, Toiletry, and Fragrance Association (CTF) notes, “The CIR... [and other programs] combined are very effective in protecting public safety and in anticipating problems before government action is necessary.”<sup>287</sup>

While the definition of “cosmetic” and the FDA’s power to regulate cosmetics has remained unchanged since 1938, the range of products that fit within the Act’s definition have included both products considered cosmetics in the traditional sense, and products which could also fit within the “drug” definition of the statute.<sup>288</sup> Some products, such as acne-treatment makeup, antiperspirant deodorant, or cavity-fighting

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The Expert Panel “deliberates” in public and reports its findings in the *Journal of Clinical Toxicology*. *See id.* The cosmetic industry is not bound to follow the Expert Panel’s findings. *See* Greff, *supra* note 260, at 246.

<sup>284</sup> *See* Donegan, *supra* note 258, at 156.

<sup>285</sup> Voluntary Registration of Cosmetic Product Establishments, 39 Fed.Reg. 10,059 (1974) (codified 21 C.F.R. pt. 710); Voluntary Filing of Cosmetic Product Ingredient and Cosmetic Raw Material Composition Statements, 39 Fed. Reg. 10,060 (1974) (codified at 21 C.F.R. pt. 720); Voluntary Filing of Cosmetic Product Experiences, 39 Fed. Reg. 10,062 (1974) (codified at 21 C.F.R. pt. 730).

<sup>286</sup> *See* 21 C.F.R. pt. 701. The cosmetic industry also provides other programs and publications to safeguard safe cosmetics and proper manufacturing; *see also* Donegan, *supra* note 258, at 157. Other programs include CTFA’s Technical Guidelines while develops programs to ensure preservatives are effective and to maintain quality control. CTFA also has Occupational, Environmental Safety and Health Guidelines to ensure that cosmetic manufacturers comply with applicable law. CTFA also has a Labeling and Environmental Manual. *See id.*

<sup>287</sup> Donegan, *supra* note 258, at 156.

<sup>288</sup> *See* Gary L. Yingling & Suzen Onel, *Cosmetic Regulation Revisited*, in *FUNDAMENTALS OF LAW AND REGULATION* 315 (Edward P. Brady et al. eds, 1997); The FDCA defines “cosmetic” as 1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and 2) articles intended for use as a component of any such articles; except that such term shall not include soap. 21 U.S.C. §321(I); FDCA §201(i). The FDCA defines “drug” as “(B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. §321(g)(1); FDCA §201(g)(1).

toothpaste, may meet the definition of both a drug and a cosmetic by combining the roles of “cleansing” or “beautifying” with the “mitigation, treatment, or prevention of a disease, or with effects on the structure or function of the body.”<sup>289</sup> In regulating these borderline products, Congress has stated that the manufacturer’s “intended” use should govern whether the product should be regulated as a cosmetic or drug.<sup>290</sup> Whether a product is regulated as a drug or as a cosmetic has ramifications both for FDA requirements and manufacturing decisions. If the FDA chooses to regulate the product as a drug, it must meet FDA standards for both efficacy and safety; if the products is treated as a cosmetic, product liability suits or FDA seizure proceedings, are the only forms of regulation.<sup>291</sup>

### ***B. State Regulation of Cosmetic Products***

In the past decade, states have increasingly played a role in regulating cosmetic products. States can independently pass safety laws under state statutes analogous to the FDCA.<sup>292</sup> Most state statutes have used cosmetic regulation as a tool to safeguard the environment.<sup>293</sup> For instance, California and other states have passed laws which limit cosmetics containing volatile organic compounds, which contribute to

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In one House version of the FDCA, both foods and cosmetics were excluded from the definition of “drug.” See FEDERAL FOOD, DRUG AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 297 (Charles Wesley Dunn ed. 1938). The Senate version of the bill did not contain this provision; consequently a product may fit both the definition of “cosmetic” and “drug.” See *id.*

<sup>289</sup>Greff, *supra* note 260, at 249.

<sup>290</sup>“The use to which the product is to be put will determine the category into which it may fall... The manufacturer of an article, through his representations in connection with the sale, can determine the use to which the article is to be put.” S. Rep. No. 361, 74<sup>th</sup> Cong., 1<sup>st</sup> Sess. § 201 (1935).

<sup>291</sup>See Laura A. Heymann, *The Cosmetic/Drug Distinction: FDA Regulation of Alpha Hydroxy Acids*, 52 FOOD & DRUG L. J. 357, 357 (1997).

<sup>292</sup>See Donegan, *supra* note 258, at 158. Donegan notes, “As a general rule, these laws have been interpreted consistently with federal law, and have provided a simple vehicle for state inspectors to supplement the authority and enforcement of the FDA under the FDCA.” *Id.*

<sup>293</sup>“Senior executives of cosmetics companies have great concern that in the Nineties, states will get carried away with environmental restrictions, which will have a great detrimental impact on our industry.” (Statement of E. Edward Kavanaugh, CFTC president), cited in Jim Ostroff, *State Environment Laws to Hit Cosmetics*, WOMEN’S WEAR DAILY (Feb. 23, 1990).

the formation of ground level ozone.<sup>294</sup> Cosmetics are also subject to state packaging requirements.<sup>295</sup> These state laws have increasingly come into tension with FDA requirements. State laws mandating that manufacturers use recycled materials could conflict with the adulteration provisions of the FDCA.<sup>296</sup> Indeed, the FDA has voiced concern that “a too-quick imposition of this requirement might pose safety problems involving migration of contaminants from the recycled materials into the product.”<sup>297</sup>

States have also attempted to regulate cosmetic safety. California’s Proposition 65,<sup>298</sup> a voter initiative adopted by California in 1986, primarily dealt with eliminating carcinogens and reproductive toxicants from drinking water.<sup>299</sup> A secondary purpose of the legislation was to impose stringent consumer warning for consumer products, such as cosmetics.<sup>300</sup> Proposition 65 required manufacturers to warn consumers if normal use of a consumer product would expose them to chemicals “known to the state of California to cause cancer or reproductive toxicity.”<sup>301</sup> Manufacturers could only escape liability by providing a “clear and reasonable” warning, and only if the manufacturer could prove that the chemical “had no effect at 1000 times the level in question.”<sup>302</sup> Cosmetic manufacturers have increasingly experienced the wrath of

<sup>294</sup>Products containing volatile organic compounds include anti-perspirants, deodorants, hairspray, hair mousse, hair gel, nailpolish remover and shaving cream. *See id.* New York, Massachusetts, Rhode Island, New Jersey, Texas, Oregon and Washington are some examples of states adopting similar laws. N.Y. COMP. CODES. R & REGS. tit. 6, § 235 (1992) ; MASS REGS. CODE tit. 330, § 7.00 et. seq. (1994) ; R.I. COMP. OF RULES OF ST. AGENCIES, Reg. No. 31, Control of Volatile Organic Compounds from Commercial and Consumer Products (1994); N.J. ADMIN. CODE tit. 7, § 27-24.1-.7 (1995); TEX. ADMIN. CODE , tit. 30, §§ 115.600,.610,.612-.617 (1995); OR. ADMIN. R. 340-22-800-860 (1994), as cited in Donegan, *supra* note 258, at 162, n. 51-56.

<sup>295</sup>*See* Donegan, *supra* note 258, at 161.

<sup>296</sup>*See* Donegan, *supra* note 258, at 161-162.

<sup>297</sup>*Id.* “[The] FDA supports the cosmetic industry’s efforts to reduce the amount of waste generated from its products as well as to incorporate recycled packaging material in the manufacture of product containers. However, cosmetic packaging, including packaging that contains recycled materials, must comply with the adulteration provisions of the Act. In mandating use levels for recycled material in product packaging, sufficient time must be granted to ensure that these new and increased uses of recycled materials do not introduce potential health hazards.” Letter from John E. Bailey, Ph.D., Acting Dir., Off. Of Cosmetics and Colors, FDA, to Thomas J. Donegan, Jr., CFTA (Mar. 24, 1993), as cited in Donegan, *supra* note 258, at 162.

<sup>298</sup>CAL. HEALTH & SAFETY CODE, § 25249.10. Proposition 65 was adopted in a referendum, garnering over 60 percent of the vote in 1987. *See* Donegan, *supra* note 258, at 159.

<sup>299</sup>*See id.*

<sup>300</sup>*See id.* Spurred by trade association groups representing the FDA-regulated industries, California enacted regulations providing for a “safe harbor” for FDA-regulated products. In 1993, environmental groups successfully challenged the “safe harbor” regulations. AFL-CIO v. Deukmejian, Dkt. No. 502541 (Sacramento Sup. Ct. Dec. 28, 1992); *See* Donegan, *supra* note 258, at 159.

<sup>301</sup>CAL. HEALTH & SAFETY CODE § 25249.7(d).

<sup>302</sup>*Id.* Regulations promulgated pursuant to Proposition 65 state that consumer products containing chemicals “known to the state to cause cancer” must bear the following warning: “Warning: This product contains a chemical known to the State of

Proposition 65.<sup>303</sup> In 1993 alone, the group, “As You Sow,” sued over 40 manufacturers of personal care products for failing to warn consumers of the presence of toluene, an ingredient in nail enamel.<sup>304</sup> Other states have sought to adopt other safety measures. New York has considered expiration dates for cosmetics.<sup>305</sup> Massachusetts is currently petitioning the FDA to have a consumer right-to-know law, similar to Proposition 65.<sup>306</sup> Massachusetts also has a bill (HB 3125) that would institute label warnings and mandatory recycling for products containing mercury.<sup>307</sup>

### C. *Enactment of FDAMA*

Through FDAMA, Congress finally introduced legislation to establish uniform national standards for cosmetics. Under the new law, states would not be able to impose labeling and packaging for cosmetic products that are in addition to or not identical to federal standards.<sup>308</sup> This section would only preempt state laws when the FDA has not specifically acted on the same aspect of labeling.<sup>309</sup> Since states have been the “most active” in packaging and labeling, the compromise reached in FDAMA assures that states will have full

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California to cause cancer.” CAL. ADMIN. CODE tit. 22, § 12601(a)(A)(1988).

<sup>303</sup> See Donegan, *supra* note 258, at 160.

<sup>304</sup> See *As You Sow v. Assorted Nail Polish Mfrs.*, Dkt. Nos. 950766, 950767, 950768 (Cal. Sup. Ct. 1993). The suits were settled under agreements to warn or to eliminate toluene as an ingredient. See Donegan, *supra* note 258, at 160.

<sup>305</sup> 143 CONG. REC. S9147 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>306</sup> *Id.*

<sup>307</sup> See *Massachusetts Mercury Declaration Bill Should Exempt Cosmetics – CFTA*, F-D-C REPORTS “Rose Sheet,” (May, 24, 1999). The bill would require the packaging and product to be labeled with “three chasing arrows,” with the words “Contains Mercury,” and with the statement “The Manufacturer of This Product is Required to Provide for Its Recycling.” A toll-free number would also be on the label so that consumers could inquire about recycling. The FDA has an exception to the prohibition of the intentional addition of mercury by allowing tiny amounts of mercury to serve as a preservative for mascara and eyeliner when there is no effective and safe nonmercurial alternative. The regulation states that mercurial preservatives for eye makeup are “warranted because mercury compounds are exceptionally effective in preventing *Pseudomonas* contamination of cosmetics, and *Pseudomonas* infection of the eye can cause serious injury, including blindness.” *Id.*

<sup>308</sup> 21 C.F.R. § 379s; FDAMA § 412(d); FDCA § 752(a); see S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344-345.

<sup>309</sup> 143 CONG. REC. S9147 (Sept. 11, 1997) (statement of Sen. Kennedy).



authority to regulate cosmetics where the FDA has not acted.<sup>310</sup> Similarly, if the FDA requires a warning on a specific ingredient, and the state wishes to impose requirements about another ingredient, the state would be free to do so.<sup>311</sup> The national uniformity provision, however, does not affect a state's ability to "exercise its police powers against unsafe cosmetic products."<sup>312</sup> For instance, if the FDA has a "warning requirement for a cosmetic ingredient about a particular concern," the state could engage in additional measures, such as a ban on the ingredient, to protect the public health; the state would not, however, be able to require additional labeling concerning the indicated ingredient.<sup>313</sup> States also remain free to seize, impose embargoes, or institute judicial proceedings to guard against adulterated, misbranded or otherwise unsafe products.<sup>314</sup> States and localities also remain free to petition the FDA under 21 C.F.R. § 10.30 to impose a state-specific requirement if an important public interest arises, and the requirement would neither violate federal law nor unduly burden interstate commerce.<sup>315</sup> States, who feel their program would benefit the nation, could further petition the FDA to make a certain regulation a national requirement.<sup>316</sup> As with OTC drugs, preemption does not apply to state product liability suits.<sup>317</sup> State requirements, such as Proposition 65, adopted by a state referendum prior to September 1, 1997, also are exempt from the national uniformity provisions.<sup>318</sup>

Originally, the bill preempted state regulations dealing with cosmetic safety. Senator Edward Kennedy decried the Republican majority's attempt to preempt state laws regulating cosmetic safety. He referred to

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<sup>310</sup>*See id.*

<sup>311</sup>*Id.*

<sup>312</sup>143 CONG. REC. S8880 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>313</sup>143 CONG. REC. S9146 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>314</sup>143 CONG. REC. S8880 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>315</sup>21 C.F.R. § 379s; FDAMA § 412(d); FDCA § 752(b); *see* S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 345.

<sup>316</sup>*See* S. Rep. No. 105-43, at 63-67 (1997), as reprinted in AN ANALYTICAL LEGISLATIVE HISTORY OF FDAMA (McKenna & Cuneo, ed. 1998), at 344-345.

<sup>317</sup>21 C.F.R. § 379s; FDAMA § 412(d); FDCA § 752(d).

<sup>318</sup>21 C.F.R. § 379s; FDAMA § 412(d); FDCA § 752(e).

the 1978 General Accounting Office (“GAO”) report which recommended that the FDA be given greater authority to regulate cosmetic safety.<sup>319</sup> The report listed 125 ingredients used in cosmetics suspected of causing cancer, 25 ingredients suspected of causing birth defects, and 20 items suspected of adversely affecting the nervous system.<sup>320</sup> Kennedy also said that the FDA has not adequately funded cosmetic regulation. Less than 30 FDA employees regulate the \$20 billion cosmetics industry, and only 2 employees actually regulate cosmetic packaging and labeling.<sup>321</sup> Referring to the United States as a “First World country with a Third World cosmetics safety system,”<sup>322</sup> Kennedy said that consumers “would be shocked” to learn that there is no federal regulation of cosmetic safety.<sup>323</sup> He argued that cosmetics are the only FDA-regulated product without adequate protection, as the FDA regulates safety standards for drugs, medical devices and food additives.<sup>324</sup>

Kennedy is not alone in his support for increased cosmetic safety. For years, Congress has initiated legislation and explored hearings to inquire into the problem.<sup>325</sup> Representative Wyden, Chairman of the House Committee on Small Businesses, said in 1989, “In my view, these regulatory gaps raise serious questions about the Food and Drug Administration’s ability to effectively oversee the cosmetics industry in this country.”<sup>326</sup> During the congressional debates on FDAMA, opponents said that finding national uniformity would be a law “directing the FDA into empty regulation.”<sup>327</sup> “The FDA not only lacks the authority to require safety

<sup>319</sup>143 CONG. REC. S8884 (Sept. 8, 1997) (statement of Sen. Kennedy). See U.S. GENERAL ACCOUNTING OFFICE, LACK OF AUTHORITY HAMPERS ATTEMPTS TO INCREASE COSMETIC SAFETY (1978).

<sup>320</sup>143 CONG. REC. S9146 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>321</sup>143 CONG. REC. S9148 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>322</sup>143 CONG. REC. S8886 (Sept. 8, 1997) (statement of Sen. Kennedy).

<sup>323</sup>143 CONG. REC. S8885 (Sept. 8, 1997) (statement of Sen. Kennedy).

<sup>324</sup>143 CONG. REC. S9150 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>325</sup>See Greff, *supra* note 260, at 244, n. 14 (citing e.g., H.R. 2244, 83d Cong. (1953); H.R. 4476, 84<sup>th</sup> Cong. (1955); H.R. 4015, 86<sup>th</sup> Cong. (1957); H.R. 4431, 85<sup>th</sup> Cong. (1957); H.R. 9153, 85<sup>th</sup> Cong. (1957); H.R. 1360, 86<sup>th</sup> Cong. (1959); H.R. 5661, 86<sup>th</sup> Cong. (1959); H.R. 1235, 87<sup>th</sup> Cong. (1961); H.R. 11,582, 87<sup>th</sup> Cong. (1962); H.R. 1235, 88<sup>th</sup> Cong. (1963); H.R. 5777, 88<sup>th</sup> Cong. (1963); H.R. 6788, 88<sup>th</sup> Cong. (1963); H.R. 8418, 88<sup>th</sup> Cong. (1963); H.R. 1235, 89<sup>th</sup> Cong. (1965); H.R. 1235, 90<sup>th</sup> Cong. (1967); H.R. 4486, 90<sup>th</sup> Cong. (1967). Senator Kennedy has said, “In fact, every time that Congress has revisited cosmetic regulation, it has resulted in a call for additional protection and additional safety measures.” H, 66.

<sup>326</sup>Heymann, *supra* note 291, at 176.

<sup>327</sup>143 CONG. REC. S9148 (Sept. 11, 1997) (statement of David Wallinga, M.D., Senior Scientist, Public Health Program, Natural Resources Defense Council, September 10, 1997) (“Who Will Act to Protect the Public from Hazardous Products in Cosmetics if S.830 Passes? No One Will!”)

testing, it also has very weak authority to require product labels that reflect health and safety concerns about cosmetics.”<sup>328</sup> Supporters of increased regulation also argue that the FDA provides only weak enforcement authority under the adulteration, misbranding and color additive provisions.<sup>329</sup>

#### *D. The Need for National Uniformity for Cosmetics*

Despite the “lenient” regulation of cosmetics,<sup>330</sup> Congress should impose a nationally uniform standard for both the safety and labeling of cosmetic products. Unlike drugs, cosmetics do not need to be regulated as heavily. Cosmetics are one of the safest products regulated by the FDA.<sup>331</sup> Indeed, the FDA devotes less of its resources to cosmetic regulation because of its extraordinary safety record.<sup>332</sup> For instance, cosmetic injuries in one study constituted .00044 percent or less than five ten-thousandths of the product sold, in other words 47,000 products out of 10.5 billion products sold.<sup>333</sup> There have been twice as many injuries caused by couches and sofas, and six times the number of injuries caused by pillows, mattresses, and beds.<sup>334</sup> While it is true that according to a study by the National Institute of Occupational Safety and Health Registry of Toxic Effects of Chemical Substances (“NIOSH”), 884 cosmetic ingredients have been found to be toxic, this list also included elements such as water, salt, and vinegar.<sup>335</sup> The GAO listed 125 ingredients found to cause cancer or birth defects, but the GAO did not perform the tests at high exposure levels and stated

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<sup>328</sup>143 CONG. REC. S9148 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>329</sup>See Yingling, *supra* note 288, at 361-62.

<sup>330</sup>See Greff, *supra* note 260, at 243.

<sup>331</sup>In 1988 hearings on cosmetic safety, former FDA commissioner Frank Young said that “Congress, when it passed the Federal Food, Drug, and Cosmetic Act, recognized that cosmetics were the lowest of the hazards, and I would still confirm that point. I believe that cosmetics are safer than other products we regulate.” *Hearing Before the Subcomm. on Reg. and Bus. Opportunities of the House Comm. on Energy and Commerce*, 100<sup>th</sup> Cong. 2d. Sess. 67 (1988) (testimony of Frank E. Young, Comm’r of Food and Drugs); Former Commissioner David Kessler also said before a House subcommittee meeting that cosmetics are “as safe as they come.” *Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Small Bus.*, 102d Cong., 1<sup>st</sup> Sess. 106 (1991) (testimony of David A. Kessler, Comm’r of Food and Drugs).

<sup>332</sup>143 CONG. REC. S8880 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>333</sup>143 CONG. REC. S8892 (Sept. 8, 1997) (statement of Sen. Jeffords).

<sup>334</sup>See *id.*

<sup>335</sup>143 CONG. REC. S8892 (Sept. 8, 1997) (statement of Sen. Jeffords).

that they did not review the applicability of the tests to cosmetics.<sup>336</sup> The report stated, “Neither we nor NIOSH has reviewed the adequacy of the tests performed or the applicability of the tests performed or the applicability of the results to exposure to the ingredients through the use of cosmetics.”<sup>337</sup> Moreover, the CIR has never denied an FDA request to review the safety of a cosmetic ingredient.<sup>338</sup>

Senator Kennedy specifically signaled out alpha hydroxy acids,<sup>339</sup> feminine hygiene products<sup>340</sup> and talc<sup>341</sup> as posing special safety threats to consumers. However, either the CIR or the FDA had thoroughly studied these products and found they were not harmful.<sup>342</sup> The CFTA says that the CIR had conducted a “thorough review” of alpha hydroxy acids, finding that these ingredients were safe for use in products of no greater than 10% at a pH of no less than 3.5.<sup>343</sup> The panel recommended that alpha hydroxy products be either formulated not to be sun-sensitive or to contain labeling stating that sunscreen is necessary. The FDA also placed the study of alpha hydroxy acids among the cosmetics programs’ top priorities in 1999.

State regulation in fact is often not even aimed at increasing cosmetic safety. Even Senator Kennedy admits that states “virtually never” use their authority to ban a particular ingredient.<sup>344</sup> Many of the state regulations pertain to state environmental law. This “pits” the environmental objectives of the state against

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<sup>336</sup> See *id.*

<sup>337</sup> See *id.*

<sup>338</sup> See *id.*

<sup>339</sup> Senator Kennedy said that between 1989 and 1996, there were “many thousands” of complaints associated with alpha hydroxy acids, such as redness, burning, blistering, bleeding, rash, itching and skin discoloration. 143 CONG. REC. S9149 (Sept. 11, 1997) (statement of Sen. Kennedy).

<sup>340</sup> Senator Kennedy noted that data indicated that the use of feminine hygiene products increased the overall risk of pelvic inflammatory disease by 73% and the risk of ectopic pregnancy by 76%. 143 CONG. REC. S9149-50 (Sept. 11, 1997) (statement of Sen. Kennedy).citing J. Zhang, AG Thomas, and E. Leybovich, *Vaginal Douching and Adverse Health Effects: A Meta-analysis*, AMERICAN J. OF PUB. HEALTH, 1997 July: 87(7), 1207-1211. Studies have also found an increased risk of cervical cancer. J, 51, citing Gardner JW, KL Shuman, ML Slattery, JS Sanborn, TM Abbott, and JC Overall, Jr., *Is Vaginal Douching Related to Cervical Carcinoma?*, AMER. J. OF EPIDEMIOLOGY, 1991 Feb; 133(4): 368-375.

<sup>341</sup> Senator Kennedy stated that talc poses a risk of ovarian cancer. 143 CONG. REC. S9150 (Sept. 11, 1997) (statement of Sen. Kennedy), citing Chang, Stella and Risch, Harvey. *Perineal Talc Exposure and Risk of Ovarian Carcinoma*, 79 CANCER ( June 15, 1997).

<sup>342</sup> The Cosmetic Ingredient Review panel had concluded in a 1996 that alpha hydroxy were not harmful. FDA records indicated that there were no reports in 1996 about feminine hygiene products. In 1994, the FDA did a study on talc and found only a nominal link between ovarian cancer and talc.

<sup>343</sup> See “AHA Further Study is Misuse of Cosmetic Resources, CFTA Says,” F-D-C Report, The Rose Sheet (March, 1, 1999.)

<sup>344</sup> 143 CONG. REC. S8878 (Sept. 8, 1997) (statement of Sen. Kennedy).

the safety requirements of the FDA.<sup>345</sup> For instance, California and Oregon require cosmetic manufacturers to reduce the size of packaging, supply reusable containers, or ensure that recyclable material composes a portion of the product.<sup>346</sup>

On the whole, the FDA – an agency of limited resources – would be better able to protect consumers against the more dangerous effects of cosmetics whose active ingredients or intended use mirror that of highly-regulated drugs by regulating such products as drugs. If the FDA had more substantial authority over cosmetic regulation, the FDA would not have an incentive to interpret the “drug” definition broadly so as to encompass the more dangerous borderline cosmetic/drug products.<sup>347</sup> The cosmetic industry’s strong safety record as well as its voluntary safety substantiation and labeling programs have allowed the industry to escape stringent FDA oversight.<sup>348</sup> Few controls are placed on cosmetics, but “the situation changes dramatically” if a cosmetic could also be classified as a drug, since it would then be subject to stricter standards of premarket testing and good manufacturing processes.<sup>349</sup> If cosmetic regulation is lax, products on the borderline which contain levels of drug ingredients<sup>350</sup> are more likely to be regulated as drugs and subject to more rigorous FDA restrictions, such as limits on the use of ingredients, labeling requirements, or preclusion of ineffective ingredients.<sup>351</sup> Many of the examples of dangerous cosmetics cited by Senator Kennedy are ones in which the problem could be better solved by regulating the product as a drug. Alpha hydroxy acids pose one example. In 1994, the FDA received 200 reports of adverse cosmetic reactions. More

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<sup>345</sup>Donegan, *supra* note 258, at 151.

<sup>346</sup>See Donegan, *supra* note 258, at 161; *See, e.g.*, CAL. PUB. RES CODE PUB. § 42300; OR. REV. STAT. § 459A650-665.

<sup>347</sup>See Greff, *supra* note 260, at 253. “The FDA’s primary motive for classifying a cosmetic as a drug is to allow the agency to apply drug regulations to the product, rather than cosmetic regulations.” *Id*; *see also* Margaret Gilhooley, *Cosmetic Regulation: Going Beyond Appearance*, SEVENTY-FIFTH ANNIVERSARY VOLUME OF FOOD AND DRUG LAW 323, 323-24 (Food & Drug Law Inst. 1984), as cited in Greff, *supra* note 260, at 253.

<sup>348</sup>See Donegan, *supra* note 258, at 162.

<sup>349</sup>Greff, *supra* note 260, at 243.

<sup>350</sup>There are a variety of approaches the FDA could take in making the cosmetic drug distinction. *See id.* at 253-257. The FDA could classify based on claims, ingredients, or risk, among others. *See id.*

<sup>351</sup>See Greff, *supra* note 260, at 272.

than 10% of those reports concerned products containing the chemical alpha hydroxy acid, a chemical which has often been suggested to be regulated as a drug.<sup>352</sup> John Bailey, Director of the Office of Cosmetics and Colors of the FDA, has stated, regarding AHAs, that “the legal scheme that applies to cosmetics. . . is clearly inadequate to products that *have a physiological effect* beyond that which occurs with traditional cosmetic products.” (emphasis added).<sup>353</sup> To solve the problem, rather than calling for regulation *by the states* of cosmetic products, the FDA should develop more consistent definitions of what constitutes a drug and what constitutes a cosmetic. The “intended use” method of characterizing borderline products provides “no clear connection to product safety,” because characterization is based on the manufacturer’s labeling of the product rather than the product’s underlying chemical composition.<sup>354</sup> Wrinkle creams best demonstrate the “incongruity” of the current system of FDA classification.<sup>355</sup> The same product – a combination of bovine albumin and water, that formed a film that temporarily smoothed wrinkles – had been marketed by different companies under different names.<sup>356</sup> The Second and Third Circuit Courts of Appeals classified the product as a drug, because the manufacturer proclaimed in advertising that the product was therapeutic rather than cosmetic in nature.<sup>357</sup> In contrast, a Maryland federal district court classified the very same product as a cosmetic.<sup>358</sup> Instead of relying on the manufacturer’s idea of “intended use,” the FDA should classify products as drugs if the cosmetic product contains an ingredient or effect that mirrors a drug.<sup>359</sup>

Greater regulation by the states does not need to be imposed because cosmetic companies will have to

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<sup>352</sup> See Stehlin, *supra* note 278.

<sup>353</sup> F.D.C. REP. (“The Rose Sheet”) (Dec. 11, 1995), at 1, 3, as cited in Heymann, *supra* note 291, at 375, n. 92.

<sup>354</sup> Heymann, *supra* note 291, at 370-371.

<sup>355</sup> See Heymann, *supra* note 291, at 366.

<sup>356</sup> See *id.*

<sup>357</sup> In *United States v. Sudden Change*, 409 F.2d 734 (2d Cir. 1969), the Second Circuit said that the cream should be characterized as a drug because it promised “a face lift without surgery.” *Id.* at 739. In *United States v. Line Away*, 415 F.2d 369 (3<sup>rd</sup> Cir. 1969), the Third Circuit said that the product was a drug because it “tightened the skin,” and was “superactive.” *Id.* at 372. See also Heymann, *supra* note 291, at 365-367.

<sup>358</sup> In *United States v. Magic Secret*, 331 F. Supp 912 (D. Md. 1971), the U.S. District Court for the District of Maryland said that claims, such as “protein,” and “astringent sensation,” made the product a cosmetic. *Id.* at 917.

<sup>359</sup> See Heymann, *supra* note 291, at 368.

meet higher standards if they wish to compete in the global marketplace. More than any other FDA-regulated product, cosmetics are a global industry.<sup>360</sup> Comprising \$21 billion in annual sales, more than 10 billion individual packages move through interstate commerce annually.<sup>361</sup> Cosmetics produced in the United States are also increasingly being sold abroad. Exports by U.S. cosmetics company were expected to top \$2.8 billion in 1999.<sup>362</sup> Given these figures, manufacturers should have flexibility to react quickly to marketplace trends, and to move in and out of geographic areas. The most successful global cosmetics company, L'Oreal, distributes its products worldwide by "conveying the allure of different cultures through its many products."<sup>363</sup> Reaching \$12.4 billion in revenues in 1999, L'Oreal has also extended its global reach by acquiring the United States' company Maybelline and in forming a joint marketing venture with a leading Japanese company. As Louis Santucci, international vice-president of the Cosmetic, Toiletry, & Fragrance Association has said, "there is a dollars and cents reality and urgency to harmonization. . . Once all of these regulations are the same and streamlined, a company can introduce many new cosmetic products at the same time all around the world. The savings and opportunities are absolutely enormous."<sup>364</sup>

In response to this trend, the United States should be shifting towards greater harmonization within its borders in order to reduce the costs of complying with diverse and complicated cosmetic regulatory systems abroad.<sup>365</sup> Compared to other nations, the United States has a weak governmental regulatory system in cosmetics. Japan's cosmetic regulatory system, for instance, is much more restrictive than that of the United

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<sup>360</sup> See Gail Edmonson, "The French Giant Stays on Top by Selling Cultural Cachet as well as Cosmetics," *BUSINESS WEEK*, June 28, 1999.

<sup>361</sup> 142 CONG. REC. S11962 (Sept. 30, 1996) (statement of Sen. Hatch).

<sup>362</sup> The Asian economic crisis led to less than expected revenues for the cosmetics industry in 1999. See Ostroff, *supra* note 293. Shipments overseas by U.S. cosmetic companies generally outpace imports by a two to one margin. See *id.*

<sup>363</sup> *Id.*

<sup>364</sup> See *id.*

<sup>365</sup> Orrin Hatch stated "A single nationwide system for regulating the safety and labeling of cosmetic products would take a great step toward helping the industry move toward the international trends in marketing. At the same time, it would be a more efficient system, since allowing individual States to impose varying labeling requirements inevitably leads to higher prices." 142 CONG. REC. S12053 (Oct. 1, 1996) (statement of Sen. Hatch)

States.<sup>366</sup> Cosmetics in Japan must meet premarket approval,<sup>367</sup> and there is an intermediate level of regulation for quasi-drugs, cosmetics which would meet both the definition of cosmetics and drug under the U.S. system.<sup>368</sup> Japan also specifies ingredients and the maximum amount allowed to be combined into cosmetic products.<sup>369</sup> In 1997, the European Union adopted two amendments which differ from U.S. requirements.<sup>370</sup> Manufacturers in Europe must maintain a “dossier” or information packet; a dossier for public access is not required in the United States.<sup>371</sup> The European Union also mandates full ingredient disclosure, including expiration dates, function of ingredients, precautions, and batch numbers.<sup>372</sup> Although premarket approval is not required for Canadian cosmetics, the Ministry of Health may require the submission of safety data; manufacturers may also be required to notify the Health Protection Branch of Health Canada of adverse reactions within 10 days of an item’s distribution.<sup>373</sup> New rules expected to be enacted this year call for mandatory disclosure of all contents in cosmetics.<sup>374</sup> Mexico requires premarket registration for cosmetic or drug products which “pose a risk to health” because they contain certain ingredients identified by the state.<sup>375</sup> Mexico also compels manufacturers to conduct certain testing for specific products; while these tests do not need to be submitted to a central regulatory agency, they must be furnished upon request.<sup>376</sup>

Expiration dates are also required in Mexico.<sup>377</sup> Sweden and Denmark have product registration for cos-

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<sup>366</sup>See Brad S. Hendrick & Linda R. Horton, *International Harmonization of Cosmetic Regulation*, in FUNDAMENTALS OF LAW AND REGULATION 491-492 (Robert E. Brady et al. eds, 1997).

<sup>367</sup>143 CONG. REC. 8886 (Sept. 8, 1997) (statement of Sen. Kennedy).

<sup>368</sup>See Hendrick, *supra* note 366, at 492-493. “Quasi-drugs” are defined as consisting of items that “have a mild effect on the body and have a definite purpose of use including prevention of nausea or other discomfort, foul breath or body odor; prevention of prickly heat and sores; prevention of hair loss, promotion of hair growth, or removal of hair; and eradication of rats, flies, mosquitoes, fleas, etc.” COSMETIC, TOILETRY, & FRAGRANCE ASS’N, CTFA INTERNATIONAL REGULATORY/RESOURCE MANUAL, 267 (4<sup>th</sup> 3d. 1995), as cited in *id.*

<sup>369</sup>See *id.* at 269.

<sup>370</sup>See Hendrick, *supra* note 366, at 491.

<sup>371</sup>See Council Directive, 76/768, art. 7a, para. 12, 1993 O.J. (L. 151), at 34 (Treaty Establishing the European Economic Community (Treaty of Rome), Mar. 25, 1957, pt. II, art. 36, 2 B.D.I.E.L. 45).

<sup>372</sup>See Council Directive 95/17, art. 2, 1995 O.J. (L 140) 27.

<sup>373</sup>COSMETIC, TOILETRY, & FRAGRANCE ASS’N, *supra* note, at 55.

<sup>374</sup>*Safety of Cosmetics to be Checked*, TORONTO STAR, (November 25, 1999).

<sup>375</sup>See Hendrick, *supra* note 366, at 499.

<sup>376</sup>COSMETIC, TOILETRY, & FRAGRANCE ASS’N, *supra* note, at 333.

<sup>377</sup>143 CONG. REC. 8886 (Sept. 8, 1997) (statement of Sen. Kennedy).



metics.<sup>378</sup> Germany, France and Australia place “more stress” on cosmetic ingredient safety than the FDA does.<sup>379</sup>

The FDA is at a crossroads. Faced with the need for harmonization, the FDA could either increase its regulation of cosmetics, and bring itself more into line with the European Union, or the FDA could encourage other nations to lower their standards to that of the United States.’ Interestingly, some countries are moving more in the direction of the United States. In 1998, Japan moved to deregulate its rigorous cosmetic regulation system, to bring it “in line with freer foreign markets and to provide Japanese consumers with more choices while ensuring their safety.”<sup>380</sup> To this effect, Japan plans to ease or eliminate requirements for licenses, shift toward the use of a negative list of ingredients,<sup>381</sup> and “place the responsibility over safety in the hands of the companies and the consumers themselves.” More significantly, Japan plans to dismantle its premarket approval for cosmetics by next year.<sup>382</sup>

Furthermore, cosmetic manufacturers already have an incentive to develop the safest products they can, such that further state regulation is unnecessary. Many manufacturers of cosmetic products conduct premarket tests, because they fear the “loss of goodwill” or reputation that could accompany reports of adverse reactions.<sup>383</sup> One cosmetic official has stated: “The law says it is prohibited for a company to produce a cosmetic product that could be injurious to the consumer under normal use. . . If I am a cosmetic official, and

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<sup>378</sup> See *id.*

<sup>379</sup> See Donald A. Davis, *Regulatory Politics: Political Aspects of Regulations Governing Cosmetics Industry*, DRUG AND COSMETIC INDUSTRY, (Nov. 1, 1992).

<sup>380</sup> *Panel Proposes More Competition in Cosmetics Market*, JAPAN WEEKLY MONITOR, July 27, 1998.

<sup>381</sup> Currently in Japan, the Ministry of Health and Welfare provides a “positive list” of cosmetic product ingredients. There is also a negative list for ingredients prohibited for use. If a cosmetic manufacturer includes ingredients located on the negative list or uses positive list elements above a certain limit, they must get the approval of the Ministry. Accordingly, on labels, the Japanese only include ingredients likely to cause problems. In contrast, in the United States and France, manufacturers are obligated to include all of the ingredients used. Japan is currently in the process of revising its rules to bring them into conformity with international standards. Japan annually receives over \$740 million a year in imported cosmetics, primarily from France, and the United States. See *Industry News: Cosmetics Industry Adopts New Standards for Labeling of Ingredients*, COMLINE PACIFIC RESEARCH CONSULTING, (January 7, 1999).

<sup>382</sup> See Ostroff, *supra* note 293.

<sup>383</sup> Heymann, *supra* note 291, at 372.

I have that as a law, why do I need some kind of review by anybody prior to marketing? . . . If you can't have happy, healthy consumers, you are going to lose a lot of money.”<sup>384</sup> Furthermore, a “bad reputation” in one product line could “spill over” into a cosmetic manufacturer’s other product lines and decrease sales.<sup>385</sup> The cosmetic industry has shown itself to be respond responsibly in the wake of cosmetic tragedies. For instance, when there was a report of a woman permanently blinded by a mascara wand, the leading manufacturer of mascara, Maybelline, led in an industry-wide cleanup of manufacturing standards and a warning to women to cease sharing mascara wands.<sup>386</sup> The report of a woman burned by an alpha hydroxy peel resulted in an industry-wide voluntary ceiling on AHA percentages in skin care products sold in retail stores.<sup>387</sup> The industry is also aware that if it does not effectively self-police, the government can pass legislation imposing governmental regulation.<sup>388</sup>

On the whole, there is no reason why the states should intrude and offer additional regulations on cosmetic safety. State regulation has the undesirable side effects of increasing costs and inhibiting the free flow of goods. Industry self-regulation added to both the practical necessity of complying with divergent international regulatory regimes and in satisfying consumer expectations has made cosmetics safe, such that there is no reason for states to add additional and unnecessary levels of protection. Further, in the few circumstances where concerns of safety may be raised, increased and uniform regulation at the federal level or reclassification of such items as drugs would be a more effective way of ensuring that consumers are not injured.

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<sup>384</sup>Cosmeceuticals: New Class of Products Offers Important Benefits for Aging Customers, *Chain Drug Rev.*, Sept. 23, 1996, at 92 (quoting Gerald McEwen, Vice Pres. For Sci., CTFA), as cited in Heymann, *supra* note 291, at 375, n. 124.

<sup>385</sup>Marc S. Moller & Paul Indig, *Products Liability Law Revisited: A Realistic Perspective*, 31 *TORT & INS. L. J.* 879 (1996).

<sup>386</sup>*See id.*

<sup>387</sup>*See id.* “Senator Kennedy displayed no interest in relating how the industry reacted to these incidents, instead honing in on the “greed” and “arrogance” displayed by the marketers’ in attempting to elicit the help of Congress in preempting states from imposing new warning labels.” *Id.*

<sup>388</sup>Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug, and Cosmetic Act*, 50 *FOOD AND DRUG L. J.* 101, 106 (1995) (historical article originally presented at the Food and Drug Law Institute – Food and Drug Administration Sixteenth Annual Educational Conference in Washington D.C. on December 12, 1972.)

### *E. The Trade-Off Between National Uniformity and State Product Liability Suits*

Critics of preemption of state tort liability might argue that the factors cautioning against liability for drugs and medical devices do not apply to cosmetics. Unlike drugs and medical devices, there does not exist as pressing a need to ensure speedy access to innovative cosmetic products. Speedy access is needed for drugs and medical devices to safeguard life and death, but quickly available cosmetic products are only necessary to satisfy consumer expectations and to generate increased sales for cosmetic companies.

However, differences in the necessity for innovation should not distract from the argument that cosmetic companies should not be subject to state tort suits. As with drugs and medical devices, Congress and the FDA should recognize that additional state regulation through state tort suits is also unnecessary. Manufacturers are only liable for foreseeable injuries.<sup>389</sup> Because most reports to the FDA regarding cosmetics pertain to allergic reactions or skin irritation, there is nothing the FDA can do to prevent these.<sup>390</sup> The FDA received 65 reports of adverse skin care products and makeup, but most of those reports were the result of either an allergic reaction or to a skin irritation.<sup>391</sup> Further, since cosmetic accidents are often random and difficult to foresee, post-accident challenges to warnings would likely have little material effect on the overall accident rate.<sup>392</sup> Courts have agreed, and manufacturers are also not generally held liable for such actions in product liability suits.<sup>393</sup> Plaintiffs also face causation problems, as generally courts hold that a plaintiff's own "idiosyncratic" allergic reaction constitutes the proximate cause of the injury rather than the cosmetic itself.<sup>394</sup> Individual users must take responsibility to become aware of their allergies and to avoid products

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<sup>389</sup> See *Gober v. Revlon, Inc.*, 317 F.2d 47 (4<sup>th</sup> Cir. 1963); *Howard v. Avon Products, Inc.*, 395 P.2d 1007 (1964).

<sup>390</sup> See Stehlin, *supra* note 278.

<sup>391</sup> See Stehlin, *supra* note 278.

<sup>392</sup> See Schafrick, *supra* note 44.

<sup>393</sup> See Moller, *supra* note 385; Annotation, Where Injury Results from Allergic (Side Effect) Reaction to a Product, 53 A.L.R. 3d 298 (1994)

<sup>394</sup> See Moller, *supra* note 385; see, e.g., *Adelman-Tremblay v. Jewel Companies, Inc.*, 859 F.2d 517, 521 (7<sup>th</sup> Cir. 1988) ("There is generally no duty to warn of harm from an unusual allergic reaction from use by a minuscule percentage of users when the risk is so rare that the injury is considered to result from a personal idiosyncrasy of the consumer." ); *Hafner v. Guerlain, Inc.*, 310 N.Y.S.2d 141 (N.Y. App. Div. 1970) (manufacturer could not anticipate reaction because plaintiff's reaction

containing the “offending ingredient.”<sup>395</sup> As with state positive legislative enactments, there appears to be no reason why states should be able to impose additional requirements. The secondary effects of tort suits – such as increased costs and delayed innovation – are simply unnecessary burdens to bear if one considers that there is no balancing factor in terms of increased safety to justify such suits.

## VII. Food

### A. *History of Food Regulation*

During the 19<sup>th</sup> century, states, pursuant to their police powers, began increasingly to regulate the food industry.<sup>396</sup> The United States Supreme Court, however, struck down many of these laws as being violative of either the Commerce or Supremacy clauses of the Constitution.<sup>397</sup> To fill the void, and to respond to an ever-increasing national food supply, Congress established the FDA and passed the 1906 Pure Food and Drug Act, the first federal enactment to protect the nation’s food supply. The Act prohibited the adulteration and misbranding of food products, and provided criminal prosecution and product seizure and condemnation as remedies for enforcement of violations.<sup>398</sup> When Congress amended the Act in 1938, it included a per se rule against all unnecessary and avoidable poisonous and deleterious substances added to food.<sup>399</sup>

was “abnormal”); *Quiroz v. Max Factor, Inc.*, 264 So.2d 263 (La. App. 1972) (plaintiff was unable to differentiate between a “caustic” reaction and an “allergic” reaction).

<sup>395</sup>See *Moller*, *supra* note 385. Indeed, a user’s failure to read the warning usually negates manufacturer liability. *see, e.g.*, *Thomas v. Clairol, Inc.*, 583 So.2d 108 (La. App. 1991) (plaintiff’s failure to read allergy test instructions was the proximate cause of injury); *See also Stehlin*, *supra* note 278. “Consumers must taken an active role in keeping product contamination and potential infection to a minimum once they take a product home.” (Statement of Gerald McEween, Ph.D., Vice President for Science, CFTC) as cited in *id.*

<sup>396</sup>See Kyle W. Lathrop, *Pre-empting Apples with Oranges: Federal Regulation of Organic Food Labeling*, 16 J. CORP. L. 885, 887 (1991).

<sup>397</sup>See, *e.g.*, *Leisy v. Hardin*, 135 U.S. 100 (1890) (invalidating an Iowa law prohibiting the sale of intoxicating beverages brewed in other states, but sold in Iowa); *Rhodes v. Iowa*, 170 U.S. 412 (1898) (invalidating an Iowa law that required a state issued permit for transport of intoxicating beverages); *see also Lathrop*, *supra* note 396, at 930, n. 22-23. After the Court’s decision in *Leisy*, Congress passed a statute which ratified the decision. *See id.* at 930, n. 25.

<sup>398</sup>See Frederick H. Degnan, *The Regulation of Food Safety*, in *FUNDAMENTALS OF LAW AND REGULATION* 163 (Robert P. Brady, ed. 1997). Under the Act, food was considered adulterated if it were prepared in ways that reduced quality, permitted passing off, rendered it injurious to health, or resulted in contamination and filth. *See id.* Food could also be considered adulterated if it “contained an added poisonous or other deleterious ingredient which may render [the food] injurious to health.” *Id.*

<sup>399</sup>See *id.* at 164.

After World War II, Congress shifted its interest to controlling for chemicals in food. A House Committee recommended in 1952 that chemicals used on or near food subscribe to the same safety requirements as that of new drugs.<sup>400</sup> To that end, in 1954, Congress adopted the Pesticide Residues Amendment, which said that pesticide residues are considered adulterated unless a tolerance or tolerance exemption was given.<sup>401</sup> Comprehensive reform occurred in 1958 through the adoption of the Food Additives Amendment.<sup>402</sup> The Amendment were designed “to ensure the safety of food ingredients and to promote public confidence in the processed food supply” by establishing a premarket approval system for “food additives.”<sup>403</sup> The Delaney Clause was also adopted. The Clause precluded the use of additives that were thought to cause cancer. The Color Additives Amendment, adopted in 1960, subjected all colorants in food, drugs, and cosmetics to a uniform premarket approval system of regulation.

The FDCA also provides FDA authority for food labeling. Section 401 of the FDCA authorized the FDA to publish “regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity.”<sup>404</sup> Unlike drugs, the FDCA does not explicitly authorize the FDA to require warnings labels on food products.<sup>405</sup> Section 403 of the FDCA also prohibits the misbranding of food under certain circumstances.<sup>406</sup>

## ***B. State Regulation of Food***

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<sup>400</sup>See H.R. Rep. No. 2356, 82d Cong., 2d Sess. (1952).

<sup>401</sup>Pub. L. No. 518, 68 Stat. 511 (1954); 21 U.S.C. § 364a.

<sup>402</sup>Pub. L. No. 85-929, 72 Stat. 1784 (1958); 21 U.S.C. § 348.

<sup>403</sup>See S. Rep. No. 795, 86<sup>th</sup> Cong., 1<sup>st</sup> Sess. 9 (1959); *see also* Degnan, *supra* note 398, at 166.

<sup>404</sup>21 U.S.C. § 341; FDCA § 401; *see also* Samia Rodriguez, *Food Labeling Requirements*, in THE FUNDAMENTALS OF LAW AND REGULATION 238-256 (Robert E. Brady et al. ed. 1997).

<sup>405</sup>See *id.* at 251.

<sup>406</sup>FDCA § 403(b) (food sold under the name of another food); § 403(d) (misleading container); § 403(f) (prominence of required information); § 403(h) (standards of quality and fill), § 403(i)(1) (common or usual name); and § 403(k) (labeling of artificial flavorings, colorings, or chemical preservative).

The combination of local interest group politics added to special geographical considerations have encouraged divergent food regulations among the fifty states.<sup>407</sup> In the early 1990s, over 380 state agencies had responsibilities similar to the FDA.<sup>408</sup> These agencies devoted most of their resources to food regulation; indeed, a 1989 study found that food regulation constituted 74% of the \$196.06 million spent for all food and drug control activities by the states.<sup>409</sup> Because fewer interest groups operated at the local level, it was often easier to pressure state legislatures to adopt favorable regulations protecting a given industry.<sup>410</sup> The passage of protectionist requirements also have the effect of benefiting consumer safety, because experienced officials in industries such as the orange juice industry in Florida had better experience in dealing with the misbranding of fruit juices.<sup>411</sup>

States also passed more stringent laws to protect consumers.<sup>412</sup> For example, some states required the labeling of dairy products containing BST, despite the fact that the FDA had been unwilling to establish the state labeling as a national standard.<sup>413</sup> California's Proposition 65 posed another example of a state requirement that imposed additional conflicting standards.<sup>414</sup> Peter Barton Hutt has stated that Proposition 65 is a "debacle of a state statute... that was so contrary to federal government policies that the commissioner of food and drugs and his general counsel felt compelled to go out... and testify against its implementation."<sup>415</sup>

<sup>407</sup>See S. Doc. No. 14, 96<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1978) (statement of Melvin Hinich & Richard Staelin, "Regulation of the U.S. Food Industry), as cited in HUTT & MERRILL, *supra* note 75, at 990.

<sup>408</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY 55 (Donna V. Porter & Robert O. Earl, ed., 1992).

<sup>409</sup>See *id.* at 56; see also *id.* at 57 (Chart which lists total food expenditures by program category).

<sup>410</sup>See S. Doc. No. 14, 96<sup>th</sup> Cong., 1<sup>st</sup> Sess., *supra* note 407. "Just as U.S. producers profit from Federal regulations which raise the costs of foreign products, local producers profit from regulations which give them a competitive edge over their competitors in other regions." *Id.*

<sup>411</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 69, citing AFDO (Association of Food and Drug Officials, 1991). Letter to the Committee on State Food Labeling, Food, and Nutrition Board, Institute of Medicine, Washington D.C., July 1.

<sup>412</sup>See FDA Restructuring, (statement of AL Clausi, Consultant on Food Research, on Behalf of the Grocery Manufacturers of America and the National Food Processors Association) (April 11, 1997) ("In the past few years, there has been an increase in the activity at the state level with regard to safety standards and warning labels.")

<sup>413</sup>BST is a naturally occurring hormone in all dairy cattle that influences milk production. See Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COL. J. ENVIR. L. 227 (1997).

<sup>414</sup>See *supra* pp. 50.

<sup>415</sup>*Advocates for Industry, Consumers Swap Ripostes at AFDO Confab*, 40 FOOD CHEMICAL NEWS (June 29, 1998) (debate

States had also passed laws to protect against misbranding. By 1992, at least 34 states had misbranding regulations pertaining to prominence.<sup>416</sup> Many of these state regulations were very detailed. For instance, Indiana required that the name on oleomargarine/margarine be in plain Gothic letters of a type size not less than 20 points.<sup>417</sup>

The FDA did little to stop the trend toward increased state regulation; indeed, it may have even accelerated it. While there are some federal statutes which preempt state food regulation,<sup>418</sup> much of federal regulation dealing with food merely sets a “low minimum standard permitting extensive state discretion.”<sup>419</sup> The reluctance of the federal government to issue laws spurred states to fill the void by developing their own food safety laws.<sup>420</sup> One of the most vivid examples is the “Reg. Penn. Dept. Ag.” Label, which indicates compliance with Pennsylvania food safety regulations.<sup>421</sup> The FDA also stopped vigorously enforcing food safety violations. In the mid-1980s, the FDA reversed its trend of prohibiting health claims in food labeling.<sup>422</sup> For instance, the FDA did not take action against the Kellogg Company when the company proclaimed that their All-Bran cereal could reduce the risk of cancer.<sup>423</sup> The FDA even stated that it was taking on a more relaxed enforcement role in regulating health claims related to the treatment or prevention of disease.<sup>424</sup>

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on “National Uniformity: What Are the Real Issues? Is Preemption the Only Solution?”).

<sup>416</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 99.

<sup>417</sup>See IND. CODE § 16-1-34-3. For more examples, see INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 99-102.

<sup>418</sup>See, e.g., 21 U.S.C. § 679 (explicitly preempting state labeling regulations under the Wholesome Meat Act).

<sup>419</sup>Lathrop, *supra* note 396, at 903-904. For example, the USDA has regulations defining cheese pizza, but it does not define a minimum amount of natural cheese nor does it preclude the use of imitation cheese. See 9 C.F.R. § 319.600, as cited in Lathrop, *supra* note 396, at 930, n. 155.

<sup>420</sup>See Nyberg, *supra* note, at 233 (starting in 1785, Massachusetts passed laws regulating labels to protect products).

<sup>421</sup>See Lathrop, *supra* note 396, at 904. 7 PA. CODE § 31.34. The Pennsylvania regulation states, “All products, whether packaged in the bakery or by a packer, processor, wholesale dealer or a distributor, shall bear the words ‘Registered with the Pennsylvania Department of Agriculture.’” *Id.*

<sup>422</sup>See Michele M. Bradley, *The States’ Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 FOOD & DRUG L. J. 650, 651 (1994). FDA regulations strictly controlled the claims manufacturer’s could make about a food’s nutritive value. See *id.*

<sup>423</sup>See *id.*

<sup>424</sup>See *id.*; 52 Fed. Reg. 28, 843 (Aug. 4, 1987).

State attorney generals filled the relaxed void of enforcement caused by the FDA's lax policies.<sup>425</sup>

### C. *The Nutrition Labeling and Education Act*

The Nutrition Labeling and Education Act ("NLEA"), like FDAMA, was largely enacted in response to the increased role of the states in regulating food labeling and advertising.<sup>426</sup> The nature of the food industry had changed, as new products increased the probability of conflicting state regulations. Further, in the 1980s, scientific investigations yielded evidence demonstrating the relationship between dietary habits and the prevalence of disease.<sup>427</sup> As a result of such studies, consumers became increasingly concerned about nutrition information.<sup>428</sup>

The NLEA amended the FDCA to require standard-format nutrition labeling for most food products.<sup>429</sup> The NLEA achieved national uniformity by preempting state standards dealing with nutrition labeling, nutrition content and health claims, and standards of identity that differed from FDA standards and by authorizing states to cooperate in enforcing the standards with the FDA.<sup>430</sup> Some state and local misbranding statutes relating to standards of identity and imitation labeling were preempted upon passage of the Act, while other sections were preempted either after 12 months of enactment<sup>431</sup> or once a study had been completed.<sup>432</sup>

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<sup>425</sup> See Bradley, *supra* note 422, at 114. States began to coordinate investigations and prosecutions via the National Association of Attorneys General, and advocated a tougher federal policy similar to that adopted under the NLEA. See *id.*

<sup>426</sup> See *id.* at 113. The stated purpose of the NLEA was to clarify and strengthen the FDA's authority to require nutrition labeling on foods, and to establish circumstances when claims made be made about a food's nutrient content. H.R. Rep. No. 538, 101<sup>st</sup> Cong., 2d Sess. 7 (1990).

<sup>427</sup> See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 4.

<sup>428</sup> See *id.*

<sup>429</sup> See Bradley, *supra* note 422, at 244.

<sup>430</sup> See Craig Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 FOOD & DRUG L. J. (1994). The NLEA's preemption provisions were passed despite opposition from the FDA and the White House. See 55 Fed. Reg. 5191 (Feb. 13, 1990); *Hearings on S. 1425 Before the Senate Comm. on Labor and Human Resources*, 101<sup>st</sup> Cong., 1<sup>st</sup> Sess. 164 (1989) (statement of Sen. Hatch).

<sup>431</sup> These provisions related to 1) manufacturer's name and address (§ 403(d)(1)); net weight (§ 403(e)(2)); and ingredient labeling. (§ 403(i)(2)).

<sup>432</sup> Preemption occurring after a mandated study included 1) food sold under the name of another food (§ 403(b)); misleading container (§ 403(d)); prominence of required label information (§ 403(f)); standards of quality and fill (§ 403(h)); common or usual name (( § 403(i) ((1)); and labeling of artificial flavorings, colorings or chemical preservatives (§ 403(k)).



Significantly, the NLEA did not preempt state safety warnings, such as California’s Proposition 65.<sup>433</sup> States also remained free to challenge false or misleading labeling.<sup>434</sup> Under NLEA, state could also enact state laws with requirements identical to federal but with different remedies and penalties.<sup>435</sup>

In a study commissioned by the FDA, the Institute of Medicine (“IOM”) reviewed the implementation of some of the NLEA provisions regarding food labeling.<sup>436</sup> The study found that more than 45 states had adopted the Uniform State Food, Drug and Cosmetic Bill, and 23 states had adopted all or parts of federal regulations by reference.<sup>437</sup> In reviewing areas of discrepancy between the states and federal governments, the study, for the most part, found that NLEA had been adequately implemented and that the federal requirements should preempt state requirements under § 403.<sup>438</sup> The study, however, found that the FDA had not adequately implemented § 403(d) dealing with container fill and deceptive packaging.<sup>439</sup> The report noted that at least seven states had enacted statutes related to deceptive packaging, and that California had determined a need to “implement additional requirements to further consumer protection. . . and [had] adopted the language of the [Federal Fair Packaging and Labeling Act of 1966] for nonfunctional slack fill.”<sup>440</sup> In making its recommendation, the report concluded that the FDA should follow the lead of California and adopt the FPLA definition for enforcing FDCA § 403(d).<sup>441</sup>

#### ***D. The Need for National Uniformity for Food***

<sup>433</sup>Pub. L. No. 101-535, § 6(c)(2), 104 Stat. at 2364.

<sup>434</sup>Pub. L. No. 101-535, § 6 (c)(1), 104 Stat. at 2364.

<sup>435</sup>See Bradley, *supra* note 422, at 123.

<sup>436</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 1. NLEA directed that that the U.S. Department of Health and Human Services, through the FDA, implement a study of the implementation of § 403 provisions. The “charge” to the Committee was to assemble a listing of relevant state and local laws dealing with the six misbranding provisions of the FDCA, to describe the provisions of each of the relevant state and local laws, and to assess the extent to which each of the provisions of § 403 are being implemented under current and proposed regulations. *See id.* at 2.

<sup>437</sup>*See id.* at 55.

<sup>438</sup>*See id.* at 8-9. The study found the implementation adequate under § 403(b) (food under the name of another food); § 403(f) (placement of required information); § 403(h) (standards of quality and fill); § 403(i)(1) (common or usual name); and § 403(k) (artificial colors, adequate flavors, and chemical preservatives); *see also id.* at 11-25.

<sup>439</sup>*See id.* at 12-14.

<sup>440</sup>*Id.* at 13.

<sup>441</sup>*See id.* at 14.

The same concerns animating national uniformity for drugs, medical devices, and cosmetics also favor national uniformity for food. Since producers must comply with conflicting state laws regarding labeling, advertising, and food formulations, cost is increased.<sup>442</sup> The Institute of Medicine study found that the cost of monitoring for nonuniformity and complying with at least 77,600 food labels exceeded \$80 million per year.<sup>443</sup> Food manufacturing and distribution is also slowed, and consumers, faced with different information and warnings, may be confused as to what is the correct formulation.<sup>444</sup> Contrary to what opponents of national uniformity may argue, adopting national uniformity for food would ultimately fulfill the original purpose of the 1906 Act. As the House Report on the 1906 Act stated:

...the laws and regulations of the different States are diverse, confusing, and often contradictory. What one State now requires, the adjoining State may forbid. Our food products are not raised principally in the States for consumption. State boundary lines are unknown in our commerce, except by reason of local regulation and laws, such as State pure food laws. It is desirable, as far as possible, that the commerce between the states be unhindered. One of the hoped for results of a national law on the subject on pure foods is the bringing about of a uniformity of laws and regulations on the part of the States within their own several borders.<sup>445</sup>

Uniformity increases food productivity, since it eliminates the need for additional production lines to comply with divergent regulations.<sup>446</sup> Uniformity also helps modernize food regulation and ensure the optimal standards of consumer protection.<sup>447</sup> Resources can be better allocated, since instead of states promulgating regulations, they can devote scarce resources to the enforcement of federal standards.<sup>448</sup> Nonuniformity also decreases innovation. The Institute of Medicine study found that the uncertainty of state regulation “limited the choice of ingredients and thereby delayed the completion of new food formulations.”<sup>449</sup>

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<sup>442</sup>Bradley, *supra* note 422, at 114.

<sup>443</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 155, 158. Many large companies employ between 1 and 10 employees who monitor state activities, receiving a salary of \$80,000 a year. *See id.* at 154. A single label change incurred a cost of \$1000. *See id.* at 158. These figures would be much higher now, as the study was conducted nearly 10 years ago.

<sup>444</sup>*See id.*

<sup>446</sup>S. Doc. 14, 96<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1978), as cited in HUTT & MERRILL, *supra* note 75, at 990.

<sup>447</sup>*See id.*

<sup>448</sup>*See id.* States can also coordinate state enforcement activities with the FDA, such as by supplementing field forces, exchanging laboratory results, and use FDA resources where expert testimony is called for.. *See id.*

<sup>449</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 156.

Changes in the food industry over the past 100 years have made national uniformity necessary. With the rise of a national distribution network, manufacturers no longer have complete control over the geographic distribution of products.<sup>450</sup> Product distributors and retailers control the market, and conduct price discounts “targeted” to performance requirements, such as minimum quantities or in-store displays.<sup>451</sup> When distributors notice regional price differences, they often buy in excess of their needs and move their products to other regions where the discount is not available.<sup>452</sup> The effect of this system is that products and labels “designed for one market will almost inevitably be distributed throughout the United States,” thereby increasing the desire of manufacturers to form consistent labels.”<sup>453</sup>

Since 1906, splintered federal regulation has only exacerbated the disharmony between state and federal regulation.<sup>454</sup> Currently, more than twelve different agencies administer more than 35 laws dealing with food regulation.<sup>455</sup> There have been recent calls to create a single agency with responsibility to administer federal food laws.<sup>456</sup> In an August 1998 report, the National Academy of Sciences report noted that the current food safety system is not equipped to meet new challenges, and that Congress should establish a uniform and centralized agency to handle safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, and education.<sup>457</sup> Having the

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<sup>450</sup> See *id.* at 49.

<sup>451</sup> See *id.*

<sup>452</sup> See *id.*

<sup>453</sup> *Id.* at 50.

<sup>454</sup> As Dychman notes, “The agencies have made attempts to coordinate their activities to overcome the fragmentation and avoid duplication or gaps in coverage, but history has shown that as time passes, such efforts frequently prove to be ineffective.” Testimony before Committee, *Duplication of Food Safety Regulation* (statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues, Resources, Community and Economic Development Division) (August 4, 1999).

<sup>455</sup> *Id.* The two primary agencies responsible for food safety are the Food Safety and Inspection Service, under the United States Department of Agriculture (“USDA”), which is responsible for the safety of meat, poultry, and some egg products; and the FDA, responsible for the safety of all other foods. Other agencies with food safety responsibilities include the Department of Health and Human Services’ Centers for Disease Control and Prevention; USDA’s Agricultural Marketing Service, Animal and Plant Health Inspection Service, Agricultural Research Service, and Grain Inspection, Packers, and Stockyards Administration; the Department of Commerce’s National Marine Fisheries Service; the Department of Treasury’s U.S. Customs Service and Bureau of Alcohol, Tobacco and Firearms; the Environmental Protection Agency and the Federal Trade Commission. See *id.*

<sup>456</sup> See *id.* “The most effective solution to the current fragmentation of the federal food safety system is consolidating food safety programs under a single agency with uniform authority.” *Id.*

<sup>457</sup> See *id.*

states regulate only adds to the confusion.

National uniformity would also further the goals of globalization.<sup>458</sup> The process of globalization is further complicated in the food industry because of different cultural attitudes about food.<sup>459</sup> For example, European countries are more prone to see so-called natural products, such as raw milk cheese, as safe.<sup>460</sup> The United States, however, imposes stricter controls on such unpasteurized products. In turn, the United States imposes less control over genetically engineered foods than does the European Union.<sup>461</sup> Uniformity is desperately needed at the international level to eliminate the discrimination facing food distributors operating internationally.<sup>462</sup> The 1989 dispute between the United States and the European Union over the use of beef growth hormone is a paradigmatic example of how differing regulations can lead to trade disputes.<sup>463</sup> The problems are only multiplied if states have their own rules based on geographical or cultural idiosyncracies.

Further, food products regulated by agencies other than the FDA enjoy national uniformity. National uniformity has been established for organic food labeling in response to increased state regulation. In 1973, Oregon passed the nation's first organic certification law in response to consumer complaints of fraud and food industry inconsistency.<sup>464</sup> Other states quickly followed.<sup>465</sup> By the late 1980s, 11 states had their own

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<sup>458</sup>See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 159. The Institute of Medicine study stated that "It seems appropriate that the nation resolve its internal... differences in preparation for effective participation in the international food trade." *Id.*

<sup>459</sup>See Echols, *supra* note 102.

<sup>460</sup>See *id.* at 530.

<sup>461</sup>See *id.* at 537-538.

<sup>462</sup>See *id.*

<sup>463</sup>See Marina Gatti, *Proposition 65: "Shoot First, Ask Questions Later," – Do the Bullets Really Work? Have We Shot the Wrong Party? Will They Call Out the Bazookas?* 47 FOOD & DRUG L. J. 739, 766 (1992). In 1989, the EU banned the sale of beef with growth hormones; the U.S. protested the ban, since the FDA had approved artificial growth hormone for livestock. See *id.*

<sup>464</sup>OR. REV. STAT. § 632.925 (1973).

<sup>465</sup>For an overview of state laws dealing with organic certification, see Lathrop, *supra* note 396, at 890-894.

rules and definitions, and 33 private agencies certified “organic” according to very diverse standards.”<sup>466</sup> To respond to the twin problems caused by the divergent labeling – namely consumer confusion and restrained interstate commerce.<sup>467</sup> Congress designed legislation to offer consistent treatment of organic foods, regarding production, processing, marketing, and retailing.<sup>468</sup> The Meat Inspection Act and the Poultry Products Act also contain express labeling provisions ensuring national uniformity.<sup>469</sup>

#### *E. Recent Action to Establish National Uniformity for Food*

Congress has sought to extend the spirit of the NLEA to achieve greater uniformity in food labeling and safety standards. Senator Judd Gregg of New Hampshire had drafted an amendment to FDAMA that would have overturned state food labeling laws.<sup>470</sup> This amendment would have effectively overturned state warning notices on the risks of eating raw shellfish that had been passed in Louisiana, California and Florida. The amendment, however, failed to make its way into the FDAMA compromise bills.<sup>471</sup> In the House, Representative Greg Ganske spoke about federal preemption of food labeling laws, but failed to offer the amendment.<sup>472</sup> Legislation was introduced in both the 105<sup>th</sup><sup>473</sup> and 106<sup>th</sup> Congress<sup>474</sup> to “finish the work begun by the [NLEA]...by providing the same uniformity for food adulteration, misbranding,

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<sup>466</sup>Consumers, Industry Win with USDA’s New National Uniformity Rule for Organic Foods, PR NEWSWIRE, (December 15, 1997).

<sup>467</sup>See Traupman, *Congress Eyes National Organic Law*, NEW FARM, Feb. 1990, at 40 (noting that “[a] national organic certification program will ease problems in interstate commerce [and further that] large supermarket chains concerned about verifying the authenticity of organic items...will more readily purchase organic food if federal standards are in place.”) *Id.* as cited in Lathrop, *supra* note 396, at 930, n. 79.

<sup>468</sup>Organic Foods Production Act of 1990, Pub. L. No. 101-624, §§ 2101-2123.

<sup>469</sup>See Edward Dunkelberger, Food Law Reform and Federal Preemption: You Can’t Have One Without the Other, LEGAL BACKGROUNDER (April 28, 1995).

<sup>470</sup>FDA Reform Legislation Begins Moving in House with Markup, 39 FOOD CHEMICAL NEWS (Sept. 22, 1997).

<sup>471</sup>FDA Reform Given Bipartisan Committee Push Toward House Floor, 5 FOOD LABELING NEWS (Oct. 2, 1997); *see also* FDA Food Reform May Play Second Fiddle to Drug and Device Issues Before Congress, 5 FOOD LABELING NEWS (February 6, 1997).

<sup>472</sup>*Id.*

<sup>473</sup>Senate Bill 2356 was introduced by Senator Pat Roberts, a member of the Senate Agriculture Committee and former Chairman of the House Agriculture Committee. 144 CONG. REC. S9044 (statement of Sen. Harkin) (July 27, 1998).

<sup>474</sup>Roberts Re-Introduces National Uniformity Bill to Preempt Food Labeling Laws, 41 FOOD CHEMICAL NEWS (May 31, 1999).

and warnings.”<sup>475</sup> The bills, introduced by Senator Pat Roberts, would prevent states from enforcing food warning requirements unless they are identical to those of the FDA.<sup>476</sup> States could petition the FDA for an exemption from the uniformity standard if it protected an important public interest, would not cause a violation of a federal law, and would not unduly burden interstate commerce.<sup>477</sup> States, however, would remain free to regulate sanitation by imposing requirements for freshness dating, open date labeling, state inspection stamps, religious dietary labeling, organic or natural designation, returnable bottle labeling, unit pricing, and geographic labeling.<sup>478</sup> The bill would also not interfere with consumer advisories for food service establishments or those recommended by the FDA’s Food Code. Opponents of the national uniformity legislation argue that Congress is merely attempting to deregulate at the state level.<sup>479</sup> The Center for Science in the Public Interest, an outspoken critic of the reform legislation, says that states pass legislation to safeguard foods, because the FDA has not acted.<sup>480</sup>

As with drugs, medical devices, and cosmetics, Congress needs to act to establish national uniformity for food regulation. The United States’ food supply is the safest in the world,<sup>481</sup> such that it is simply unnecessary for states to impose an additional layer of regulation. Further, the states should remain free to enforce federal laws as they deem fit, and to participate in efforts such as the Interstate Milk Shippers and the Interstate Shellfish agreements.<sup>482</sup> As with drugs and cosmetics, states should also be able to petition the FDA to

<sup>475</sup> *Senate Bill Would Establish Uniform Food Safety Labeling*, 6 FOOD LABELING NEWS (August 5, 1998.)

<sup>476</sup> Brian Folkerts of the National Food Processors Association said that the bill was “a first step forward in eliminating potential food label confusion for consumers.” *Roberts Re-Introduces National Uniformity Bill to Preempt Food Labeling Laws*, 41 FOOD CHEMICAL NEWS (May 31, 1999).

<sup>477</sup> *See id.*

<sup>478</sup> *Id.*

<sup>479</sup> *GMA Aiding Committees in Drafting ‘National Uniformity’ Food Legislation*, FOOD LABELING NEWS (May 20, 1998.)

<sup>480</sup> *See id.* The CSPI argues that since 1976, staff in the FDA’s Center for Food Safety and Applied Nutrition has declined by 20%. *See id.*

<sup>481</sup> *See* Robert Sussman, *Proposed Changes in Food Safety Legislation*, 49 FOOD & DRUG L. J. 421, 421 (1994). (“These proposed changes will build and improve upon the world’s most sophisticated and effective food protection system and will culminate in the reduction of pesticides in our food supply and the ecosystem.”)

<sup>482</sup> *See National Uniformity Proposal by GMA will Accommodate Many Concerns of State Officials*, 39 FOOD CHEMICAL NEWS

make an idea a national requirement.<sup>483</sup> This would be consistent w/ the Institute of Medicine’s finding that state laws are often a good starting point for FDA regulation where FDA rules are not deemed adequate.<sup>484</sup>

## VIII. Conclusion

As Peter Barton Hutt said, “A nationwide market, policed by a strong and powerful nationwide regulatory agency, demands a nationwide regulatory system to go with it. By establishing clear regulatory goals and requiring public accountability, the agency will be more efficient and more effective”<sup>485</sup> Establishing national uniformity for all FDA-regulated products would go a long way toward ensuring the scientific supremacy of the FDA and in ensuring a continued supply of the safest foods, drugs, and cosmetics to American consumers. Uniform national standards will cut costs and eliminate the burdens of complying with fifty-one different state regimes. Uniformity will also work in tandem with the goal of achieving international uniformity in ensuring the safety of the world’s food, drug and cosmetic supply. While the FDA has a different regulatory system for each product, the system that the FDA creates for each product is an appropriate mechanism for achieving the optimal level of safety. If the FDA and the United State want to strive for a uniform system of regulation of FDA products, it must make further revisions to FDAMA and establish that FDA rules and regulations will preempt state product liability suits.<sup>486</sup> The FDA cannot achieve national uniformity without ensuring to manufacturers and food suppliers that compliance with FDA standards will allow them to escape liability. Further, if the goal of national uniformity is one worth pursuing – as this paper argues

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(June 16, 1997).

<sup>483</sup> See *id.*

<sup>484</sup> See *supra* p. 69. For instance, the Institute of Medicine recommended that California’s adoption of the FPLA’s definition for nonfunctional slack fill be followed by the FDA. See INSTITUTE OF MEDICINE, FOOD LABELING: TOWARD NATIONAL UNIFORMITY, *supra* note 408, at 12-14; CAL. BUS & PROF. CODE § 12606 (does not require proof that the slack fill is misleading or deceptive).

<sup>485</sup> *Hearings on H.R. 3200 Food Amendments and the Animal Drug Availability Act of 1996 Before the Subcommittee on Health and the Environment*, 103<sup>rd</sup> Cong. (May 1, 1996) (statement of Peter Barton Hutt on behalf of the Grocery Manufacturers Association of America and the Cosmetic, Toiletry, and Fragrance Association).

<sup>486</sup> This paper does not suggest that preemption of federal standards would be unlimited. FDA compliance defense should be structured as compliance with FDA regulatory standards rather than mere FDA approval. “Any conclusion that the FDA’s approval represents a considered assessment that an approved drug’s therapeutic benefits outweigh its risks, however, is unwarranted without a manufacturer investigation that complies with FDA requirements for adequate and well-controlled studies of the new drug, accurate reporting of the results of those tests, and truthful responses to inquiries by the FDA.” Green, *supra* note 149, at 481, 496; see also Rissier, *supra* note 13, at 1415-1421 (discussion of qualified federal preemption).

it is – it is would not make sense to have a suboptimal national uniformity system; surely, if the FDA establishes national standards, but yet, manufacturers or suppliers could still be held liable for failing to follow a state-imposed duty “more protective” than the federal standards, the benefits gleaned from national uniformity – in terms of decreased costs and increased innovation – will suffer.